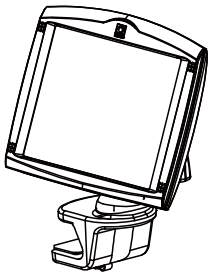
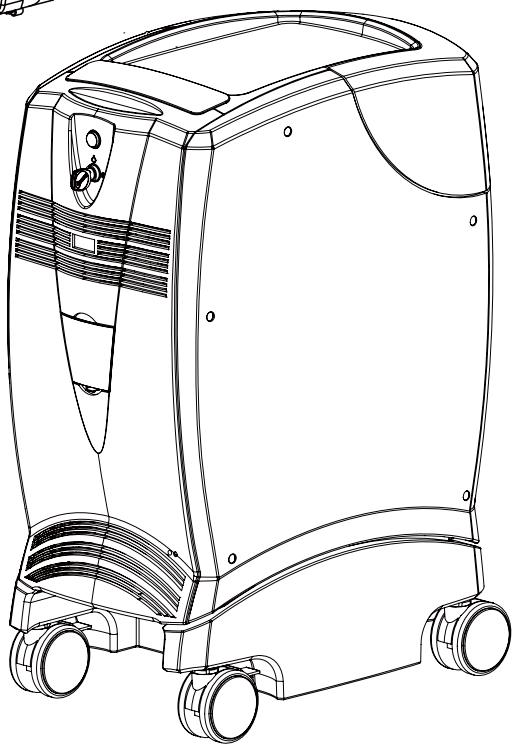
NIDEK

Multicolor Laser Photocoagulator

MC-500





OPERATOR'S MANUAL

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Original instructions

Eye & Health Care
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Use this device properly and safely.

⚠ BE SURE TO READ THIS MANUAL BEFORE USING THE DEVICE.

⚠ THIS MANUAL CONTAINS ONLY INFORMATION TO UNDERSTAND THE MAIN BODY OF THE PHOTOCOAGULATION SYSTEM. FOR THE OPERATION OF THE PHOTOCOAGULATION SYSTEM, REFER TO THE OPERATOR'S MANUAL OF THE APPLIED DELIVERY UNIT.

This Operator's Manual contains information necessary for the operation of the NIDEK Multicolor Laser Photocoagulator MC-500. This manual includes the operating procedures, safety precautions, and specifications.

Especially, the cautions for safety and operating procedures must be thoroughly understood before using the device. Keep this manual handy to verify use whenever necessary.

Use of the photocoagulation system is limited to treatment of ocular diseases by qualified physicians in accordance with the instructions in the operator's manuals of the main body and delivery unit. The physicians are responsible for the application of this photocoagulation system and the treatment of various eye diseases.

Use of the photocoagulation system outside the scope of this manual may cause unexpected troubles and adverse events.

There are no parts within the device that require servicing by the user other than fuses.

If you encounter any problems or have questions about the photocoagulation system, please contact NIDEK or your authorized distributor.

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1. BEFORE USE

1.1 Device Outline

The NIDEK Multicolor Laser Photocoagulator MC-500 is a laser photocoagulator for ophthalmology with the light source of wavelengths 647, 577, and 532 nm.
As the conventional laser photocoagulators, the MC-500 can be used for retinal photocoagulation for treatment of ocular fundus diseases like diabetic retinopathy, age-related macular degeneration, retinopathy of prematurity, and retinal detachment, or for laser iridotomy and laser trabeculoplasty for treatment of glaucoma.

Three wavelengths can be selected for the treatment beam: red (647 nm), yellow (577 nm), and green (532 nm - same as the green laser photocoagulator). The most appropriate wavelength of the treatment beam can be selected according to the diseases and other conditions. For example, red laser beam (647 nm) has high transmittance and is suitable for photocoagulation of a part under bleeding tissue. Yellow (577 nm) and green (532 nm) laser beams are highly absorbed by hemoglobin and suited for photocoagulation of capillary aneurysm.

The device incorporates two types of lasers (diode-pumped solid state laser and laser diode) which enable efficient obtainment of laser beam oscillation of each wavelength. As the conventional device, various types of laser delivery units can be used as described in “9.3. Delivery Units” (page 101). Therefore, transpupillary photocoagulation can be performed using various delivery units such as slit lamps and binocular indirect ophthalmoscope.

1.2 Intended Use

The NIDEK Multicolor Laser Photocoagulator MC-500 is intended to be used in ophthalmic surgical procedures, including retinal and macular photocoagulation, iridotomy and trabeculoplasty.

1.3 Principles

The laser photocoagulation is thermal coagulation of tissue (protein) with heat generation by absorption of the laser energy that reaches through ocular media into the pigment of retina or choroid. Normally, protein coagulates and becomes white when its temperature rises to approximately 70ºC or more. The degree of coagulation can be judged by observing the white spot with the ophthalmoscope (such as slit lamp and binocular indirect ophthalmoscope). The generation of white spot varies slightly within the same treatment beam emission range. The higher the laser power is and the longer the laser emission time is, the greater the generated heat becomes. As the heat becomes greater, coagulation effect spreads to surrounding tissues. Also take it into consideration that transmission of the laser energy by the ocular media and the depth of area of heat generation differ according to the wavelength.

The MC-500 splits the pumped laser beam into the aiming and treatment beams to control them separately. Then the aiming and treatment beams are combined and lead to the fiber optic cable. The output end of the fiber optic cable is connected to the delivery unit. The laser beam is formed into a spot of a certain size in the optical system for the laser beam. Then the laser beam is emitted to the target area. The delivery unit is equipped with a protective filter which protect the physician’s eyes from exposure to the treatment laser beam reflected from the patient’s eye or contact lens.

1.4 Classifications

Classification under the provision of 93/42/EEC (MDD): Class IIb

The MC-500 is classified as a Class IIb device.

Laser classification: Class 4 laser product

The MC-500 is classified as a Class 4 laser product.

A Class 4 laser product is considered to be an acute hazard to the skin and eyes from direct or scattered radiation.

Form of protection method against electric shock: Class I

The MC-500 is classified as a Class I device in which protection against electric shock and does not rely on basic insulation only, but which includes additional safety grounding of accessible conductive parts in the fixed wiring in such a way that accessible conductive parts cannot become live in the event of a failure of the basic insulation.

For of protection against electrical shock (applied parts): Type B applied part

The MC-500 is provided with a Type B applied part.

A device with a Type-B applied part contains an internal electrical power source providing an adequate degree of protection against electric shock in regards to allowable leakage currents and reliability of the protective ground connection (if present).

Conformity to electromagnetic compatibility standard

The MC-500 conforms to the EMC standard of IEC60601-1-2: 2001+A1: 2004.

Degree of protection against harmful ingress of water: IP20

The degree of protection by the enclosure of the MC-500 main body is classified as IP20, and that of the foot switch is classified as IPX8.

An IP20 system is protected against an ingress of solid foreign objects, such as a finger having a diameter of 12.5mm or greater, however, it is an ordinary system without protection against an ingress of liquids. Be careful not to get water on the main body and control box.

An IPX8 system is a waterproof system provided with an enclosure preventing the effects caused by immersion in water.

Degree of safety in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide

The MC-500 should not be used in the presence of a flammable anesthetic mixture with air, or a flammable anesthetic mixture with oxygen or nitrous oxide caused by leakage or a discharge.

Methods of disinfection recommended by manufacturer

The MC-500 does not include any parts that need sterilization or disinfection.

Mode of operation

The MC-500 is classified as a continuous operating device.

Classification by transference

The MC-500 is classified as a transportable device.

1.5 Symbol Information

	Indicates that the degree of protection against electric shock is of a Type B Applied Part.
	Indicates that when the switch is pressed to this symbol side, power is not supplied to the device.
	Indicates that when the switch is pressed to this symbol side, power is supplied to the device.
	Indicates the state of the key switch. When the switch is in this position, the system is not operational.
	Indicates the state of the key switch. When the switch is turned to this symbol position, it automatically returns to the ON position and then the system becomes operational.
	Indicates the fuse rating.
	Indicates that the device must be supplied only with alternating current.
	Indicates that important descriptions are contained in the operator’s manual and that the operator must refer to the operator’s manual prior to operation or maintenance.
	Indicates the switch to be pressed to stop laser beam emission in case of emergency.
	The system is in normal condition while this indicator is on, and the system is in abnormal condition when it is blinking.
	Indicates that the treatment beam is in READY mode and laser emission is enabled.
	Indicates that the treatment beam is in STANDBY mode and laser emission is disabled.
	Indicates that the power output of the laser beam is shown in the display.
	Indicates that the emission time of the laser beam is shown in the display.
	Indicates that the spot size of the laser beam from the slit lamp is shown in the display.
	Indicates that the interval time in the Repeat mode is shown in the display.
	While this indicator that is on the left of the aiming level indicator is on, the aiming beam is turned off.
	Indicates the counter display.
	Indicates the date of manufacture.
	Indicates the manufacturer.
	Alerts the operator to hazardous laser exposure.
	Indicates the fiber optic cable connector.
	Indicates that this product must be disposed of in a separate collection of electrical and electronic equipment in EU.

1.6 Precautions in Patient Selection

Caution should be exercised when selecting patients with the following conditions to be treated with the MC-500:

Patients with progressive eye disease
Patients who have difficulty in eye fixation due to nystagmus or condition that may induce nystagmus
Infant
Patients with aphakic eye or ocular disease
Patients with low intraocular transparency due to a disease that causes intraocular hemorrhage
Diabetic patients
Patients with myopic choroidal neovascularization
Patients with acute attack of primary angle closure (with corneal edema)
Patients with late glauocoma or extremely high intraocular pressure

1.7 Contraindications

Use of the MC-500 is contraindicated in patients with foveal choroidal neovascularization or myopic choroidal neovascularization.

1.8 Adverse Events and Adverse Device Effects

Potential adverse events accompanying the use of the MC-500 may include, but are not limited to the following:

[Adverse events]

- Increased intraocular pressure
- Narrowed visual field
- Dark adaptation disturbance
- Hyphema
- Lenticular opacity
- Hyphema
- Corneal damage
- Epimacular membrane
- Corneal burns
- Reduction in intraocular pressure
- Bullous keratitis
- Choroidal detachment
- Localized cataract
- Posterior synechia
- Closure of perforating wound
- Choroidal hemorrhage
- Posterior vitreous membrane detachment
- Chorioretinal atrophy (or its spread)
- Abscess dissemination in vitreous body
- Effects of false photocoagulation on retina
- Macular edema (Cystoid macular edema)
- Formation of subretinal connective tissue
- Effects of false photocoagulation on fovea
- Subretinal fibroplasia
- Vitreous hemorrhage
- Color vision deficiency
- Corectopia
- Corneal opacity
- Retinal tear
- Corneal opacity
- Retinal tear
- Reduction in visual acuity
- Scleral perforation
- Dilated pupil
- Postoperative iritis
- Optic neuritis
- Paracentral scotoma
- Myopia
- Retinal hemorrhage
- Phthisis bulbi
- Reduction in contrast sensitivity
- Development of neovascularization
- Peripheral anterior synechia (PAS)
- Retinal detachment (Tractional retinal detachment)
- Excessive photocoagulation
- Atrophic creep (Expansion of laser scar)
- Formation of retinochoroidal collateral veins
- Branch retinal artery occlusion

[Adverse device effects caused by failure of the photocoagulation system]

If any abnormality is found in the main body or delivery unit in the pre-operation function check, stop using the main body and the delivery unit.

If use of the main body and delivery unit becomes impossible due to any abnormality in them, interruption and reattempt of laser emission may be required.

With the failed main body or delivery unit, intended treatment result may not be obtained and the health hazard or unexpected adverse events described in [Adverse events] below may occur.

2. SAFETY PRECAUTIONS

In this manual, signal words are used to designate the degree or level of safety alerting. The definitions are as follows.

⚠ **CAUTION** • Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury or property damage accident.

⚠ **WARNING** • Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

⚠ **DANGER** • Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury or property damage accident.

Even situations indicated by "⚠CAUTION" may result in serious injury under certain conditions. Safety precautions must be strictly followed at all times.

2.1 Storage, Transport, and Installation

⚠ **CAUTION** • The following are common conditions that need to be met during storage, transport, and installation of the photocoagulation system:

- Not exposed to direct sunlight or ultraviolet rays.
- Not exposed to rain or water
- No chemicals or organic solvents are present.
- No poisonous gas, sulfur, salt or large amount of dust is contained in the air.
- Level and stable (10º or less) without vibration and shock.
- A place where the following environmental conditions for storage and transport (= packed condition) and installation (=unpacked condition) are satisfied:

<Storage, transport>.....Temperature: 0 to 50ºC (32 to 122ºF) / Humidity: 10 to 95% (non-condensing)

<Installation> ..... Temperature: 15 to 30ºC (59 to 86ºF) / Humidity: 30 to 75% (non-condensing)

- **After transport or storage, or when the air-conditioning is turned off, the internal structure of the photocoagulation system may be outside the specified environmental conditions for use. In such a case, turn on the air-conditioning and leave the system sit at least for an hour before turning on power to the system.**
- **Follow the instructions below to transport the photocoagulation system:**
  - Disconnect the delivery unit from the photocoagulation system main body and store them in the shipping carton for each (keep the shipping carton) to transport the system to other facilities.
  - Avoid bumping the photocoagulation system when carrying or transporting it even if it is stored in the shipping carton so that the alignment of optical components is not affected.
  - To avoid condensation, care should be taken so that the temperature varies as little as possible during transport.

⚠ CAUTION

- **Follow the instructions below to install the photocoagulation system:**
  - Only properly trained people are allowed to install or adjust the photocoagulation system.
  - Install the photocoagulation system in a place level (10º or less) and stable without vibration or shock.
  - To avoid troubles from condensation, let the photocoagulation system sit until the temperature of it becomes almost the same as that of the area for installation.
  - Avoid installing the photocoagulation system where it is exposed to the direct flow of air conditioning to prevent malfunction caused by temperature change and condensation.
  - Do not install the photocoagulation system in a high-temperature, high-humidity, or dusty place to avoid adverse effects on the lens and mirror.
  - Install the photocoagulation system leaving 10 cm or more between the wall and the ventilation hole on the side panel of the main body so that the system can radiate heat properly.
- **Follow the instructions below to move the position of the photocoagulation system:**
  - To avoid impact or shift of the optical axis caused by inertia force, fix movable parts of the slit lamp in advance.
  - Never pull the power cord or a connecting cable to transport the device.
  - Never tilt the system more than 10º to avoid falling of them that may injure personnel and damage the system.
- **Be sure to attach or remove the delivery unit to the main body with the key switch turned OFF.**
  - If the delivery unit is attached or removed with the key switch turned ON, an error may occur.
- **This device has been tested and found to comply with the limits for medical devices in IEC60601-1-2: 2001+A1: 2004. These limits are designed to provide reasonable protection against harmful interference in a standard medical installation. This device generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference to other devices, which can be determined by turning the device on and off, the operator is encouraged to try to correct the interference by one of the following measures:**
  - Reorient or relocate the receiving device.
  - Increase the separation from other devices.
  - Connect the device into an outlet on a circuit different from that to which the other device(s) are connected.
  - Consult the manufacturer or field service technician for help.
- **The International Electrotechnical Commission sets the essential requirements for electrical and electronic equipment that may disturb, or be disturbed by, other equipment. The MC-500 complies with these requirements as shown in the tables in "10 EMC (Page 103)". Follow the guidance in the tables for use of the device in an electromagnetic environment.**

2.2 Handling Power Cord and cables

⚠ CAUTION

- **Follow the instructions below to handle the power cord and cables of the photocoagulation system:**
  - To avoid failure or malfunction, connect the cord and cable to the specified connectors securely.
  - To avoid break of cable that may cause short-circuit or fire, always pull the plug, not the cord, when unplugging the power cord or do not coil the cord tightly or put it under heavy objects.
  - To avoid melting of the sheath, do not run the cord or cable near devices that produce heat.
  - If the inside wires of the cord or cable are exposed, replace it with a new one immediately to avoid short-circuit, electric shock, or fire.
  - If any cord or cable are hot or touching them turns the power on or off, replace them with new ones immediately to avoid fire or malfunction.
  - To avoid injury or malfunction caused by break of wire or fall, never drag the system by holding the cord or cable when transporting the system.
  - To avoid malfunction or failure of the system, connect the cable plug to the specified delivery unit connector on the front panel of the MC main body.
- **Follow the instructions below to handle the power cord and cables of the photocoagulation system:**
  - Use a grounded power outlet which meets the power requirements labeled on the main body to prevent damage to the system and electric shock.
  - To avoid electric shock, insert or disconnect the plug of the power cord with dry hands.
  - Do not overload the electrical output. Abnormal heat generation may occur and result in fire.
- **Follow the instructions below to handle the fiber optic cable:**
  - Loosely coil the fiber optic cable with a radius of 10 cm or more to prevent break or deterioration.
  - To avoid deterioration in laser delivery performance, be careful not to bump the fiber optic cable (from dropping or hitting).
  - To avoid deterioration in laser delivery performance, be careful not to soil or damage the tip of the plug of the fiber optic cable plug, especially when inserting the plug into the FIBER connector.
  - To avoid laser emission from the delivery unit which is not being selected, connect the plugs of the fiber optic and connecting cables from the delivery unit to the specified channels.

2.3 Use

⚠ WARNING • **Use of controls or adjustments, or performance of procedures other than those specified herein may result in hazardous radiation exposure.**

• **Follow the instructions below to handle the photocoagulation system:**

- Before using the main body and the delivery unit of the system, read their operator's manuals and thoroughly understand the safety precautions and operating procedures.

  [Use of the system with procedures specified herein may result in unexpected system malfunction or adverse events.]

- Only service technicians properly trained by NIDEK is allowed to install and composite the photocoagulation system. Only physicians are allowed to perform emission of treatment beam for surgery.
- Never modify or touch the internal structure of the photocoagulation system to avoid electric shock or malfunction.
- Never soil or scratch the lens and mirror to maintain the performance of treatment beam emission.
- Use the system with at least an assistant in the same room.

  This is to prepare for the case such as electric shock. It is desirable that the assistant is trained in resuscitation.

- Be sure to use accessories specified by NIDEK.
- Be sure to use delivery units specified for the MC-500.
- Be sure that the photocoagulation system is used under proper climate control with appropriate temperature and humidity.
- If the temperature or humidity has changed substantially due to transport of the photocoagulation system, leave the system sit for 30 minutes or more before using it.

  [Use of the system with procedures specified herein may result in unexpected system malfunction or adverse events.]

- Prepare backup measures for the surgeries to be performed in case of failure of the photocoagulation system.
- Be sure to properly explain to the patients about expected results and potential adverse events preoperatively.
- Take care when using the system with other devices that are used in contact with patients:

  Interference of electromagnetic waves or other radiation may induce hazardous conditions.

  Contact coagulation by an electrosurgical knife may cause electric shock or burning.

- The MC-500 main body is intended to be used in combination with the NIDEK SL-1800, or Carl Zeiss Meditec 30SL/M or SL 130. Never use it singularly or in combination with other medical devices.

  [Use of the system with procedures specified herein may result in unexpected system malfunction or adverse events.]

⚠ **WARNING**

- **Follow the instructions below before starting the photocoagulation system:**
  - Make sure that there is no flammable anesthetic gas in the operating room prior to starting the photocoagulation system to prevent ignition or explosion caused by treatment beam emission.
  - All personnel in the operating room except the operator and patient must wear recommended (or equivalent to the recommended) safety goggles during operation of the photocoagulation system to protect their eyes. In addition, instruct them never to gaze directly at the laser beam even when wearing the safety goggles because eyes may still become damaged.

    <Recommended goggles>

    For red - Yamamoto Kogaku Co., Ltd., YL300 He-Ne

    For yellow and green - Yamamoto Kogaku Co., Ltd., YL-717 Nd-YAG SHG
  - Prior to starting the photocoagulation system, perform operation checks and record the results to prevent accidents. See "7 ADMINISTRATION AND CHECKS (Page 85)".
  - To prevent an interruption of laser emission which causes the necessity to perform the surgery again due to any system abnormalities, stop using the photocoagulation system if any abnormality is found in the checks before use and function checks above.
- **Follow the instructions below while the photocoagulation system is operational:**
  - Never gaze at the aiming beam that is emitted from the laser aperture directly or direct it toward personnel to prevent accidental exposure to the laser beam. Always pay attention to the direction of the aiming beam.
  - Never leave the photocoagulation system unattended while it is operational to prevent accident caused by unauthorized personnel. If the operator has to be away from the system, turn the key switch to the off position, remove the key, and store it in the customary place.
- D**uring installation and operation of the photocoagulation system, observe the following instructions about EMC (electromagnetic compatibility):**
  - Do not use the photocoagulation system simultaneously with other electronic equipment to avoid electromagnetic interference with the operation of the photocoagulation system.
  - Do not use the photocoagulation system near, on, or under other electronic equipment to avoid electromagnetic interference with the operation of the photocoagulation system.
  - Do not use the photocoagulation system in the same room as other electronic equipment such as life-support equipment, equipment that has major effects on the life of the patient and results of treatment, or any other measurement or treatment equipment that involves small electric current.
  - Do not use the photocoagulation system with portable and mobile radio frequency communication systems because that may have an adverse effect on operation of the photocoagulation system.
  - Do not use cables or accessories that are not specified for the photocoagulation system because that may increase the emission of electromagnetic waves from the photocoagulation system and decrease the immunity of the system to electromagnetic disturbance.
- **If any abnormal indication (other than treatment beam emission condition) is displayed on the LCD controller or control box during operation of the photocoagulation system, see "8 TROUBLESHOOTING GUIDE (Page 93)" and perform the suggested actions.**

⚠ CAUTION

- **Follow the instructions below to handle the LCD controller.**
  - Never press the LCD controller with a hard object such as a ball-point pen. Keep magnetic objects away from the LCD controller.
    Malfunction may result.
  - Do not operate the LCD screen with wet hands.
    Water intrusion may result in malfunction of the photocoagulation system.
  - There may be a few constantly-lit, missing or dead pixels in your LCD screen which are a characteristic of the LCD screens. This does not represent a failure of the LCD screen. continuously use the monitor.
- **When connecting to peripheral equipment like a PC with LAN connector via a medical facility network, insert or connect an isolation transformer between medical electrical equipment and the networked device (such as HUB), and the networked device and any other electrical equipment.**
  Depending on the types or numbers of other electrical equipment connected to the network, electric shock or malfunction/failure of the electrical equipment may occur. For installation of the network isolation transformer, consult NIDEK or your authorized distributor.
- **Follow the instructions below to emit the laser beam:**
  - When the treatment beam (wavelength: 532, 577, and 647 nm) of the MC-500 is emitted to tissue, the following symptoms may occur. Pay attention to the direction of the aiming beam to avoid emission of the treatment beam onto eyes or skin inadvertently.
    Eye symptoms: damage to parts such as the cornea or blindness
    Skin symptoms: pain, burning.
  - Make sure that there is no reflective object in the optical path of the laser prior to laser beam emission to prevent exposure to the reflected laser beam.
  - Set the treatment beam to a low power output initially, and then increase it until the desired effect can be obtained to avoid emission of excessively intense treatment beam. Always return the light intensity to the minimum level after every examination.
  - It has been reported that the risk of vitreous hemorrhage is higher in Scan mode than when Scan mode is not used. Therefore, start the treatment using the single spot with the lowest power output, gradually increase the power output, then execute photocoagulation in Scan mode with the power output with which the intended effects can be achieved. After the treatment, be sure to return the power output to the lowest level.
  - If an idirect lens is used for laser emission to protect the cornea and the vitreous body from becoming damaged, do not set the spot size of the treatment beam larger than about 200 µm.
  - Place the photocoagulation system in the state in which treatment beam emission is impossible (for example, when only observation of the eye is performed) (STANDBY mode) except when laser beam emission in intended in order to prevent inadvertent treatment beam emission.

⚠ CAUTION

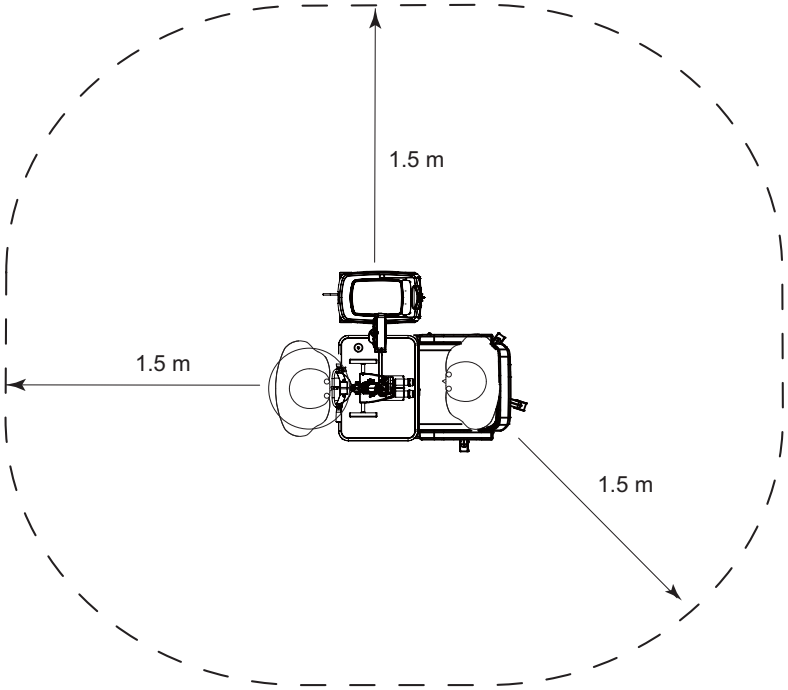
- Perform the procedure below to confirm that the photocoagulation system is in a proper condition for treatment beam emission. (If any abnormality is found in Step 2., ask NIDEK for check and maintenance.)
  1. Project the aiming spot on a surface that is not specular.
  2. Confirm that the intensity of the illumination spot is even around the center as shown to the right and that lowering of the intensity or partial blocking of light does not occur.

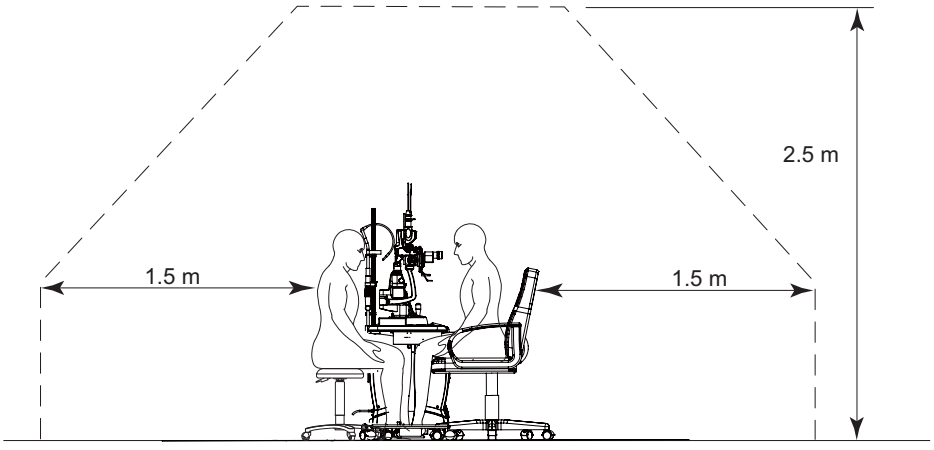
2.4 Patient environment

⚠CAUTION The patient environment is the volume of space in which contact can occur between the patient and any part of the system or between the patient and any other person(s) touching the system.

If a person handling a conductive part of the system comes into contact with a patient at the same time, hazard may occur due to leakage current exceeding the value specified in the applicable standard. Be careful not to touch patients when connecting or removing cords.

Use devices that comply with IEC60601-1 in the patient environment. If any device that does not comply with IEC 60601-1 is to be used, use an isolation transformer or common protective grounding.





2.5 After Use, Maintenance, and Checks

⚠ **WARNING** • Follow the instructions below for after use of the photocoagulation system:

- When the photocoagulation system is not being used, turn it OFF and put the dust cover over it to maintain the performance of laser beam emission.
- If the photocoagulation system will not be used for a long period of time, disconnect the power cord from the grounded power outlet to avoid spark discharge caused by moisturizing of dust settled on the blades of the plug.
- If the photocoagulation system will not be used for a long period of time, remove the batteries from the remote control (optional).
- After using the system, remove the power cord plug from the power outlet to disconnect the system from the power source.

  When removing the power cord plug from the power outlet, secure a space of at least 50 cm. Working in insufficient space may cause injury.

• Follow the instructions below for maintenance of the photocoagulation system:

- Only service technicians properly trained by NIDEK may disassemble and repair the photocoagulation system.
- Use only the specified fuses for replacement to avoid malfunction or fire.
- Never use organic or abrasive solvent to clean the exterior of the photocoagulation system including the LCD controller to avoid damage to the exterior and maintain the operability.
- Never scratch the laser reflective mirror of the delivery unit to maintain the performance of laser beam emission.
- If the LCD controller becomes dirty, wipe it with a soft cloth or gauze soaked in with ethanol. Other cleaning methods may damage the touch screen. After the cleaning, when the accessories are dry, be sure to visually check their exterior.

• Follow the instructions below to check the photocoagulation system:

- Ask NIDEK or your authorized distributor for calibration of the laser beam power output and emission time, and measurement of the earth resistance and earth leakage current once a year to maintain the performance of laser beam emission.
- Before returning the main body to NIDEK, wipe the surface of the main body with a clean cloth dampened with alcohol to prevent infection.

2.6 Disposal

⚠ CAUTION

- When disposing the main body, ask NIDEK or your authorized distributor.
  Inappropriate disposal may contaminate the environment.
- Follow local governing ordinances and recycling plans regarding disposal or recycling of device components when disposing the foot switch or the delivery unit.
  Inappropriate disposal may contaminate the environment. Ask your authorized distributor for the detail.
- When disposing of packing materials, sort them by material and follow local governing ordinances and recycling plans.
  Inappropriate disposal may contaminate the environment.

2.7 Safety Devices

[Key switch]

For safety, only the designated key allows operation of the MC-500 so that only authorized person may use the system. The key cannot be removed when it is in the ON (⊙) position. When the system is not in use, remove and store the key in a secure place.

[STATUS button]

This button is used to select the status that the treatment beam can be emitted (READY mode) or not (STANDBY mode). Unless this button is pressed to make the system enter the READY mode, the treatment beam cannot be emitted even if the foot pedal is pressed unintentionally. Keep the photocoagulation system in STANDBY mode by pressing this button except when using the treatment beam.

[EMISSION indicator]

While the photocoagulation system is operational (key is in the ON (⊙) position), the EMISSION indicator on the control box lights up and the EMISSION indicator is displayed in the LCD controller to call the operator's attention.

[EMERGENCY OFF button]

If an emergency situation occurs with either the patient or the photocoagulation system, and the operator judges that the operation should be stopped immediately, this button should be pressed. By pressing this button, the safety shutter is activated to shut down the laser and the entire photocoagulation system is turned OFF. To restart the system, turn the key switch to the OFF (◯) position, and then to the ON (⊙) position again.

[Emission time manual off function]

This function stops emission of the treatment beam instantly by releasing the foot pedal even before the set emission time. By this function, an unintentionally intense burn can be prevented by judgement of the physician.

[Aiming off function]

This function places the photocoagulation system in the STANDBY mode automatically not to emit the treatment beam when the aiming beam is turned OFF. While the aiming beam is OFF the system cannot enter the READY mode even by pressing the STATUS button. This function prevents emission of the treatment beam without the aiming beam.

[Fiber Optic Cable Detection Function]

Connection of the plug of the fiber optic cable to the main body is detected so that the laser beam cannot be emitted when the fiber optic cable is disconnected from the main body.

[Protective filter]

To protect the physician's eyes from any kind of hazardous radiation reflected from target tissue during the treatment beam emission, each delivery unit has a protective filter. If this filter is not set in the observation path, the treatment beam cannot be emitted even by pressing the foot switch.

* For the binocular indirect ophthalmoscope delivery unit, the protective filter is fastened in the optical path for observation.

[Self-diagnostic function]

If any abnormality occurs to the photocoagulation system, this function detects it, blocks the optical path of the treatment beam with the shutter automatically, and stops the photocoagulation system.

When the photocoagulation system stops, the EMISSION indicator on the control box blinks, the beep sounds are produced, and the operator is informed of the occurrence and symptom of the error with an Interlock or Error number in the INTERVAL indicator.

[REMOTE connector (for detecting the remote interlock)]

This connector is for connecting a signal line of an external switch with which to stop the photocoagulation system automatically.

This connector can be connected to the access door switch of the operation room to stop the system in case of unintended door opening, or can be connected to the external switch so that a physician other than the one who is conducting the surgery can stop the system by his/her judgment in the case of danger during the treatment beam emission.

If this method of system stoppage is unnecessary, connect a short plug here.

[Misoperation Indication Function]

If a procedural mistake is made while attempting to project the aiming beam or emit the treatment beam, an abbreviated description of the misoperation is indicated in the TIME display and beeps sound. This function aids in the understanding of correct operating procedures and allows continuation of treatment beam emission even if the system has been misoperated.

[Manual reset function]

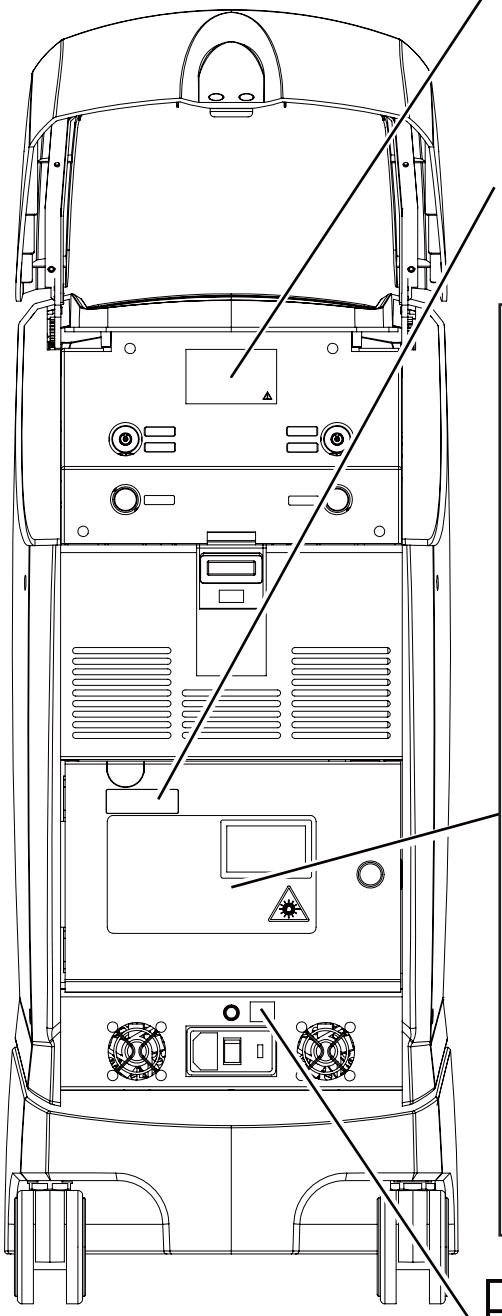
The system does not restart automatically after stoppage due to unexpected events such as a power outage even when the problem has been solved and the photocoagulation system is ready to be restarted.

It depends on the operator's decision whether to restart the photocoagulation system. To restart the system, turn the key switch to the OFF (◯) position once and then turn it to the ON (⊙) position.

2.8 Labels

Cautionary labels are provided on the main body.

[Rear view]



CAUTION -Cable contains fiber optics, use extreme care when handling and storage. DO NOT bend, kink, drop or apply excessive stress or the fiber will break.

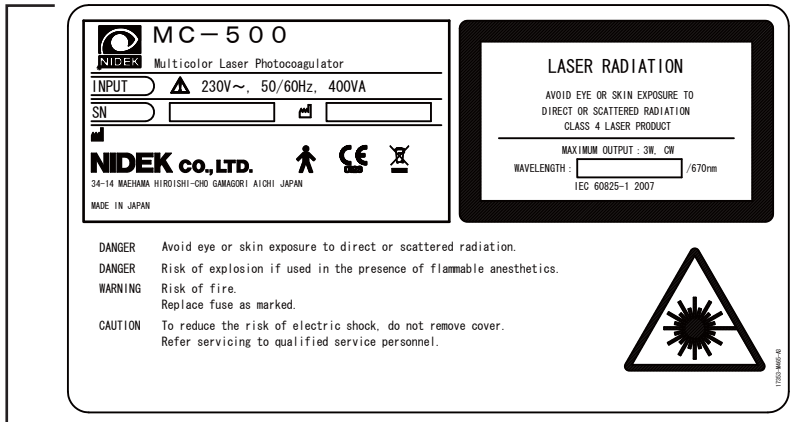
or

For France

ATTENTION – La cable contient une fibre optique. Faites tres attention lors de sa manipulation et de son stockage. Ne pas le plier, le tordre, le laisser tomber ou appliquer un poids excessif dessus sinon la fibre se cassera.

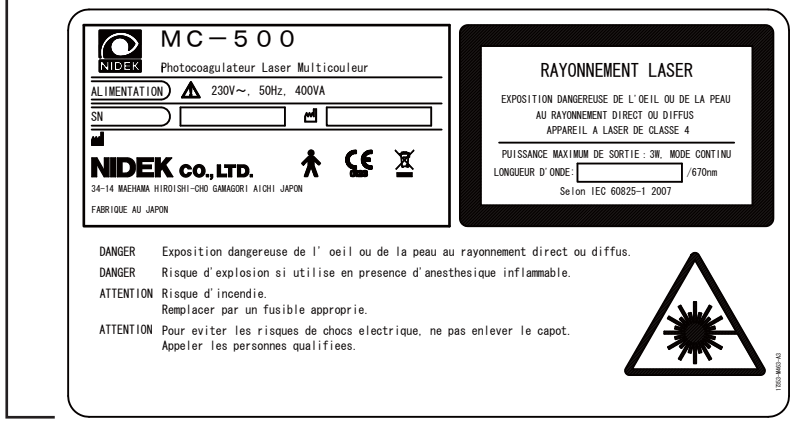
See "2.2 Handling Power Cord and cables (Page 9)".

PHOTOCOAGULATEUR LASER MULTICOULEUR
FOTOCOAGULATORE LASER MULTICOLORE
MULTICOLOR LASER-PHOTOKOAGULATOR
FOTOCOAGULADOR LÁSER MULTICOLOR
17353-M470-A



or

For France

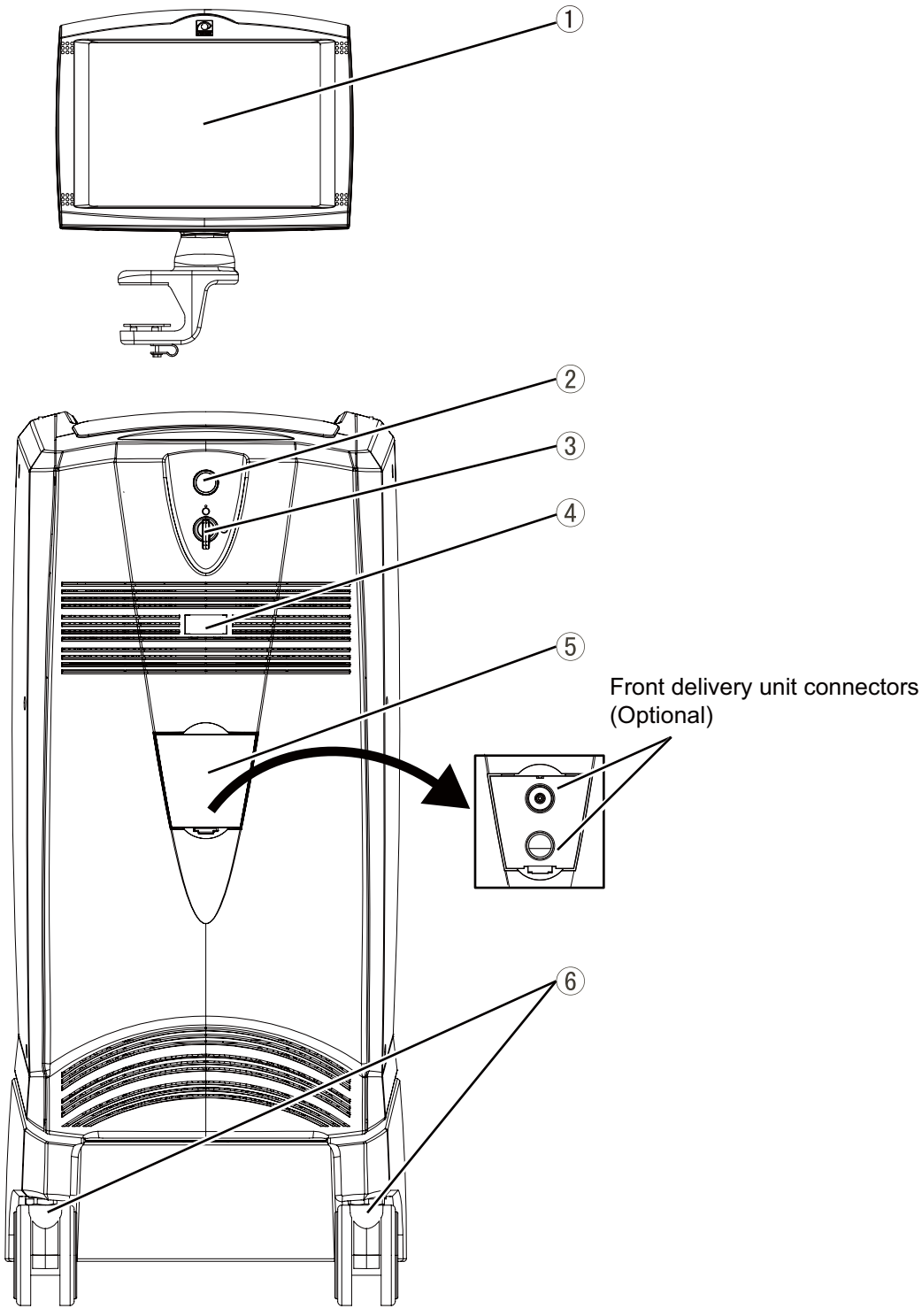


See "2.2 Handling Power Cord and cables (Page 9)".

F1, F2
T 2.5A 250V

3. DEVICE CONFIGURATION

3.1 Main Body - Front View



①LCD controller

Attached to the motorized optical table and used to set and display the laser emission conditions.

②Emergency Off button

Used to stop the photocoagulation system in case of emergency. When this button is pressed, power to the entire system is turned off, and all operations of the system stop.

* To restore the system, return the key switch to the OFF ◯ position once, then turn it to the ON ⊙ position.

③Key switch

Used to start or stop the system. To start the system, turn this switch to the ON (⊙) position. To stop the system, turn the key switch to the OFF (◯) position. If the operator has to be away from the system, be sure to stop the system, remove the key and store it to a secure place.

④Light receptor

Receives signals from the remote control (optional).

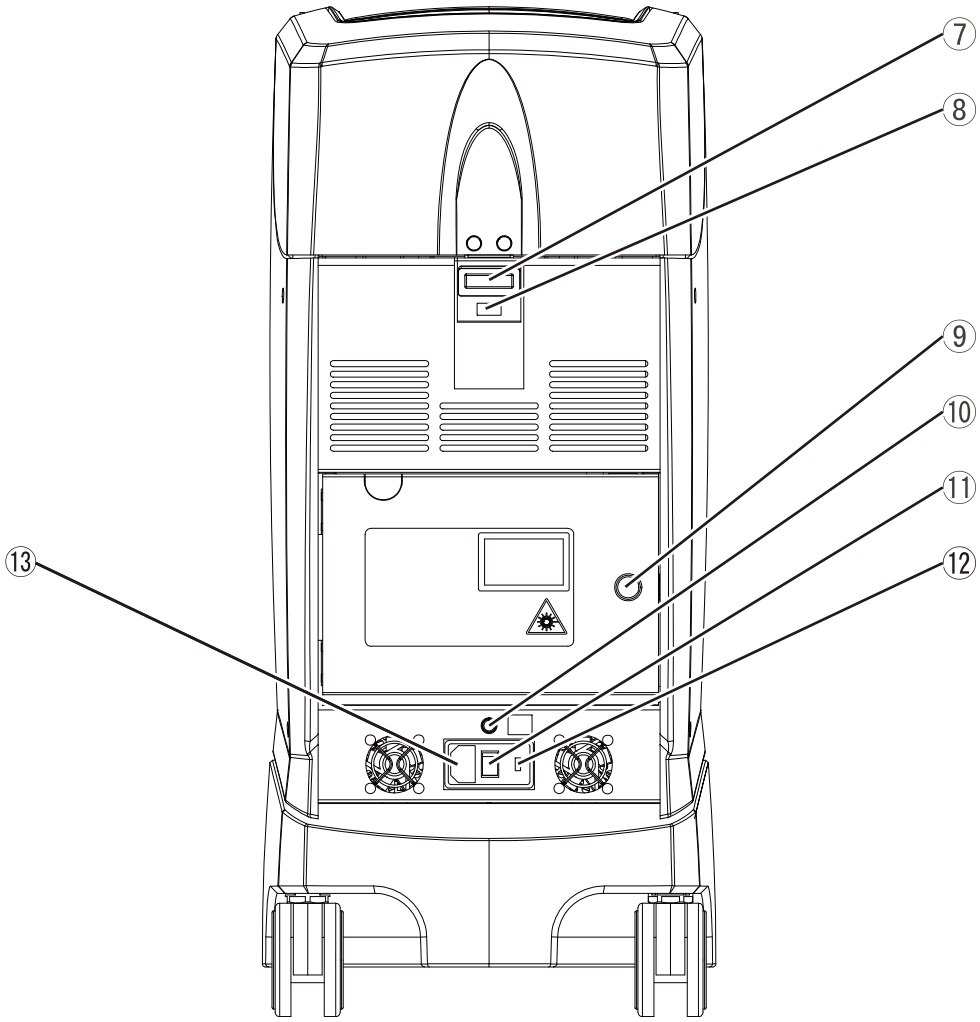
⑤Front cover

Optional front delivery unit connectors are under the cover.

⑥Casters

Flip up the lock lever of the casters to move the main body. When the place for installation is decided, lock the casters by flipping down the lock lever.

3.2 Main Body - Rear View (with rear cover closed)



⑦**Connector access cover button**

Pressed to open the connector access cover.

⑧**Light receptor**

Receives signals from the remote control (optional).

⑨**Rear cover button**

Used to open the rear cover. “PUSH” is inscribed on the cover button.

⑩**Pilot lamp**

Indicates the power status of the system. When the power cord is connected to the power outlet and the master switch is turned on (|), the pilot lamp illuminates in three seconds, and when the master switch is turned off (◯), the pilot lamp goes out in three seconds.

⑪**Master switch**

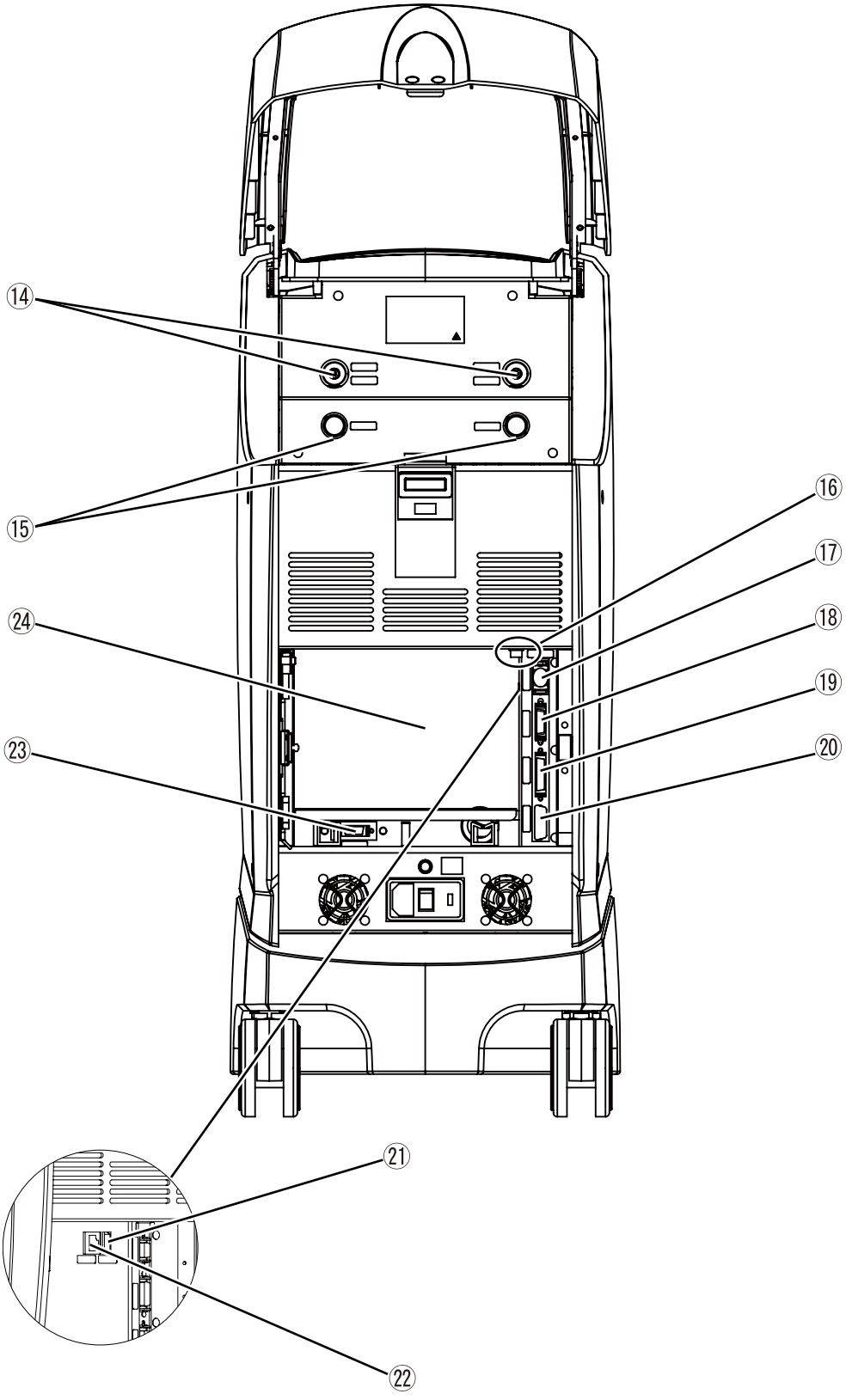
When the power cord is connected to the power outlet and the master switch is turned on (|), the system power is turned on, and when the master switch is turned off (◯), the system power is turned off.

⑫**Fuse holder**

⑬**Power inlet**

Used to connect the power cord.

3.3 Main Body - Rear View (with rear cover open)



⑭Fiber optic cable connector[*1]

The fiber optic cable plug of the delivery unit is connected here. The CH1 “FIBER 1” is for the slit lamp or combination delivery unit, and the CH2 “FIBER 2” is for the Binocular Indirect Ophthalmoscope (hereafter called BIO) delivery unit.

⑮Delivery unit connector[*2]

The cable plug of the delivery unit is connected here. The CH1 “DELIVERY 1” is for the slit lamp or combination delivery unit, and the CH2 “DELIVERY 2” is for the BIO delivery unit. For the scan delivery unit, the fiber optic cable plug of the scan delivery unit is connected to the ⑲ scan connector.

⑯Foot switch connector

The cable plug of the foot switch is connected here.

⑰Remote connector

The remote plug used for emergency stop of the system in the case of entry of an unauthorized person in the room or a short plug is connected here.

⑱Control box connector

The cable plug of the control box (optional) is connected here.

⑲Scan connector

The scan delivery unit cable plug is connected here. The fiber optic cable plug of the scan delivery unit is connected to the CH1 “FIBER 1” connector.

⑳M1 connector

Not used

㉑USB-A connector

The barcode / magnetic card reader can be connected. With the barcode / magnetic card reader, patient IDs can be loaded into the main body.

㉒LAN connector

A LAN cable can be connected to transfer measurement data from the main body to an external computer.

NIDEK service personnel will perform the connection and setting with permission from a network administrator of each facility.

㉓Monitor connector

The LCD controller is connected here.

㉔Foot switch storage

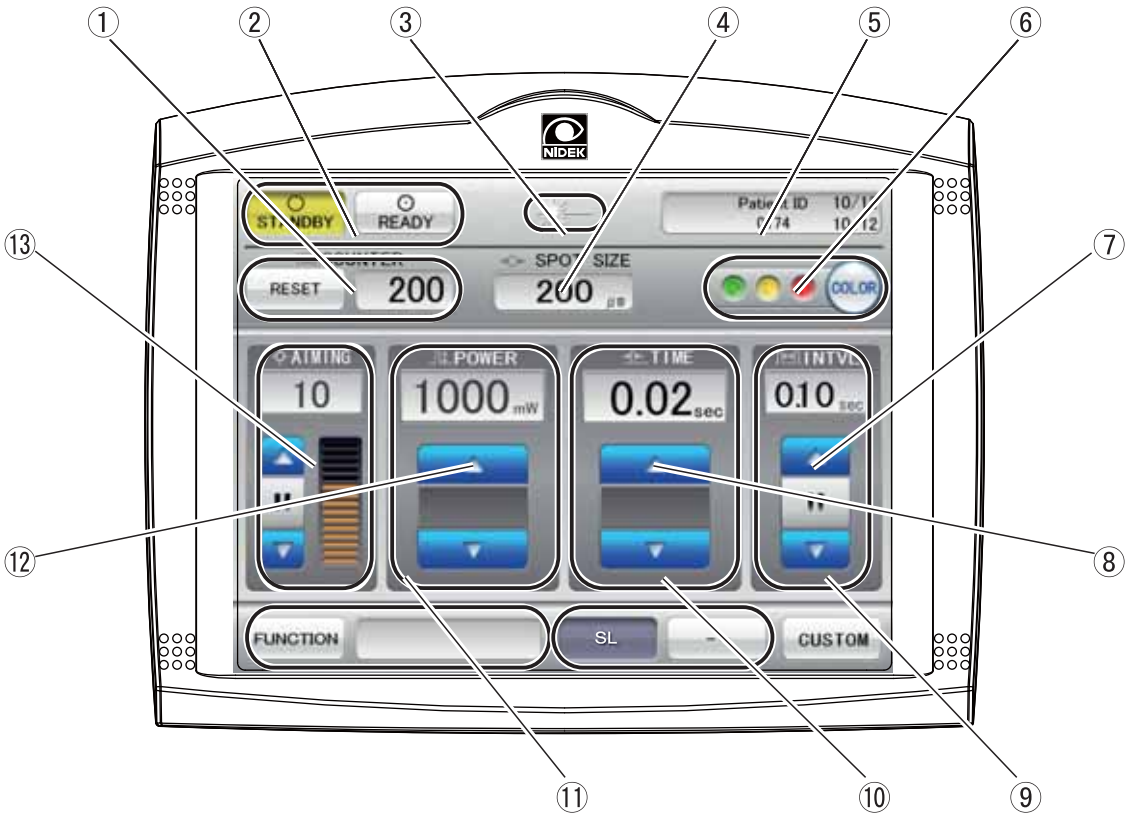
Used to store the foot switch.

***1. If the optional CH2 connector is attached, the “FIBER 2” connector cannot be used. Use the “OP FIBER 2” connector on the front panel of the main body.**

***2. If the optional CH2 connector is attached, the “DELIVERY 2” connector cannot be used. Use the “OP DELIVERY 2” connector on the front panel of the main body.**

3.4 LCD Controller (Main Screen)

3.4.1 For slit lamp or binocular indirect ophthalmoscope delivery unit



①COUNTER RESET button

Pressing this button returns the counter to “0” (zero).

The number of the treatment laser beam emission is displayed to the right of this button in the range of 0 to 9999. When “COUNTER Reset” is selected in the Select Summary Display screen, pressing this button displays the summary of treatment in the screen. For details, see “3.7.4.1 Select Summary Display screen (Page 44)”.

②STATUS buttons

Used to toggle the treatment beam between STANDBY and READY modes. When the treatment beam will not be emitted, set the system in STANDBY mode for safety.

STANDBY button (Treatment beam cannot be emitted)

When the treatment beam will not be used, press the STANDYBY button for safety. When the STANDBY button is pressed, the button is yellow.

When “Change to STANDBY” is selected in the Select Summary Display screen, the summary of treatment is displayed in the screen when the STANDBY mode is enabled. For details, see “3.7.4.1 Select Summary Display screen (Page 44)”.

READY button (Treatment beam can be emitted)

When the treatment beam will be used, press the READY button. When the READY button is pressed, the button is green.

③EMISSION indicator

Indicated while the key switch is turned ON (⊙). While the treatment beam is emitted, the EMISSION indicator appears in the color of the treatment beam being emitted.

④SPOT SIZE display

Shows the diameter of the treatment beam spot (unit - μm) in the range from 50 to 1000 μm. When the BIO delivery unit is used, nothing is displayed in the SPOT SIZE display of the LCD controller. In the control box (optional), the type of the delivery unit is shown as “bio”.

⑤Message display

Shows error or other messages.

⑥COLOR indicators and button

Shows the color of the selected treatment beam.

COLOR button

Used to select the color of the treatment beam. Each time this button is pressed, the color changes as “GREEN” → “YELLOW” → “RED”... The power setting is not changed when the color is changed. However, a power larger than the maximum value for each color (GREEN 1,700 mW, YELLOW 1,500 mW, RED 800 mW) cannot be set.

⑦ INTERVAL display and buttons

Shows the interval time in Repeat mode (unit - second). In Single mode, there is no indication.

INTERVAL buttons (Only in Single mode)

Used to toggle between the Single and Repeat modes and set the interval time in Repeat mode (unit: second). Each time the upper button is pressed, the interval time becomes longer as “no indication (Single mode)” → “0.05” → “0.10”...”1.0.” Each time the lower button is pressed, the interval time becomes shorter and finally the interval time indication disappears (Single mode). The  button in the middle is used to toggle the Repeat mode between on and off.

⑧TIME display and buttons

Shows the treatment beam emission time (unit - second).

If the operating procedure for projection of the aiming laser beam or operation of the treatment beam is improper, an abbreviated error indication is indicated in the control box (optional). For details, see “8.2 Indications of Misoperation (Page 97)”.

TIME buttons

Used to set the treatment beam emission time (unit - second).
Each time the upper button is pressed, the emission time becomes longer. Each time the lower button is pressed, the interval time becomes shorter. The emission time changes in increments of 0.01 second between 0.01 and 0.10 second, in increments of 0.05 second between 0.10 and 0.50 second, in increments of 0.10 second between 0.50 and 1.00 second, and in increments of 1.00 second between 1.00 and 3.00 seconds.

⑨CUSTOM button

Used to display the Custom screen to change parameters such as function settings or memory. For details, see “3.7 CUSTOM Screen (Page 39)”.

⑩Channel buttons

Used to toggle the channel (CH 1 or CH 2) to be used. The left button is for CH 1 to which the slit lamp delivery unit is connected. The right button is for CH 2 to which the BIO delivery unit is connected. An abbreviation of the connected delivery unit is displayed above each buttons as follows: “SL” (slit lamp delivery unit), “BIO” (BIO delivery unit), and “ - - “ (no delivery unit connected).

⑪Function display

Displays the function assigned to the Function button. For details of the assignable functions, see “3.7.3 Select Function screen (Page 42)”.

Function button

Used to execute the function assigned to the Function button.

⑫POWER display and buttons

Shows the power output of the treatment beam (on the cornea) (unit - mW). The maximum power output differs depending on the color of the treatment beam.

POWER buttons (LCD controller), POWER control (Control box)

Used to set the power output of the treatment beam (on the cornea) (unit - mW).
When the POWER control is turned, the power output can be set in increments of 10 mW between 50 and 500 mW, and in increments of 50 mW in the higher range. When the POWER control is turned while it is pressed, the power output can be set in increments of 100 mW.

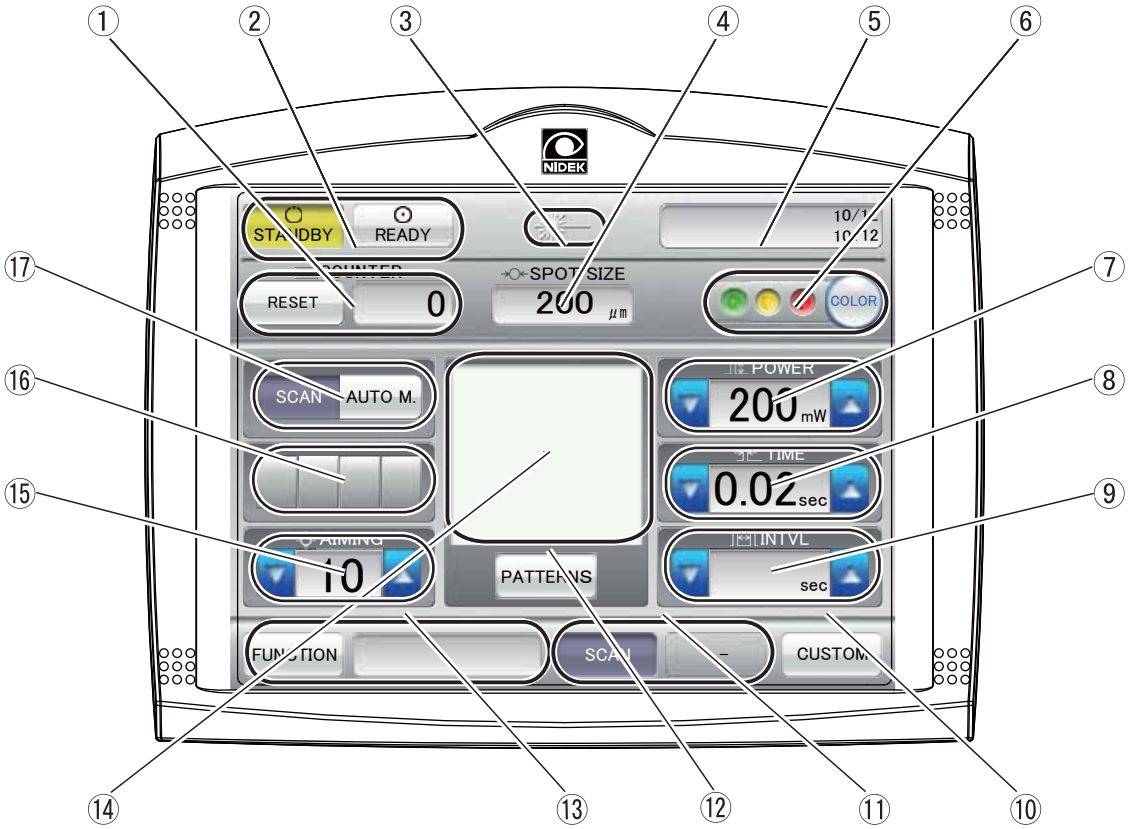
⑬AIMING display and buttons

Shows the intensity of the aiming beam with a bar graph. There is no indication when the aiming beam is off.

AIMING buttons

The intensity of the aiming beam can be set in 15 levels. The maximum level is 15. Each time the upper button is pressed, the aiming beam becomes more intense. Each time the lower button is pressed, the aiming beam becomes less intense, and finally goes out. The button in the middle is used to toggle the aiming beam between on and off.

3.4.2 For scan delivery unit



①COUNTER RESET button

Pressing this button returns the counter to “0” (zero).

The number of the treatment laser beam emission is displayed to the right of this button in the range of 0 to 9999. When “COUNTER Reset” is selected in the Select Summary Display screen, pressing this button displays the summary of treatment in the screen. For details, see “3.7.4.1 Select Summary Display screen (Page 44)”.

②STATUS buttons

Used to toggle the treatment beam between STANDBY and READY modes. When the treatment beam will not be emitted, set the system in STANDBY mode for safety.

STANDBY button (Treatment beam cannot be emitted)

When the treatment beam will not be used, press the STANDYBY button for safety. When the STANDBY button is pressed, the button is yellow.

When “Change to STANDBY” is selected in the Select Summary Display screen, the summary of treatment is displayed in the screen when the STANDBY mode is enabled. For details, see “3.7.4.1 Select Summary Display screen (Page 44)”.

READY button (Treatment beam can be emitted)

When the treatment beam will be used, press the READY button. When the READY button is pressed, the button is green.

③EMISSION indicator

Indicated while the key switch is turned ON (⊙). While the treatment beam is emitted, the EMISSION indicator appears in the color of the treatment beam being emitted.

④SPOT SIZE display

Shows the diameter of the treatment beam (unit - μm) spot in the range from 50 to 500 μm.

⑤Message display

Shows error or other messages.

⑥COLOR indicators and button

Shows the color of the selected treatment beam.

COLOR button

Used to select the color of the treatment beam. Each time this button is pressed, the color changes as “GREEN” → “YELLOW” → “RED”... The power setting is not changed when the color is changed. However, a power larger than the maximum value for each color (GREEN 1700 mW, YELLOW 1500 mW, RED 800 mW) cannot be set.

⑦ POWER display and buttons

Shows the power output of the treatment beam (on the cornea) (unit - mW). The maximum power output differs depending on the color of the treatment beam.

POWER buttons (LCD controller), POWER control (Control box)

Used to set the power output of the treatment beam (on the cornea) (unit - mW).

The power can be increased by pressing the △ button and decreased by pressing the ▽ button. The power output can be set in increments of 10mW between 50 and 500mW, and in increments of 50 mW in the higher range.

⑧TIME display and buttons

Shows the treatment beam emission time (unit - second).

If the operating procedure for projection of the aiming laser beam or operation of the treatment beam is improper, an abbreviated error indication is indicated in the control box. For details, see “8.2 Indications of Misoperation (Page 97)”.

TIME buttons (in AUTO M. or Single mode)

Used to set the treatment beam emission time (unit - second).

Each time the △ button is pressed, the emission time becomes longer. Each time the ▽ button is pressed, the interval time becomes shorter. The emission time changes in increments of 0.01 second between 0.01 and 0.10 second, in increments of 0.05 second between 0.10 and 0.50 second, in increments of 0.10 second between 0.50 and 1.00 second, and in increments of 1.00 second between 1.00 and 3.00 seconds.

TIME buttons (in SCAN mode)

Used to set the treatment beam emission time (unit - second).

Each time the upper button is pressed, the emission time becomes longer. Each time the lower button is pressed, the interval time becomes shorter. The emission time changes in increments of 0.01 second between 0.01 and 0.03 second.

⑨INTERVAL display and buttons

Shows the interval time in Repeat mode (unit - second). When a scan pattern is selected in SCAN mode, there is no indication.

INTERVAL buttons

Used to toggle between the Single and Repeat modes and set the interval time in Repeat mode (unit: second).

Each time the △ button is pressed, the interval time becomes longer as “no indication (Single mode)” → “0.05” → “0.10”...”1.0.” Each time the ▽ button is pressed, the interval time becomes shorter and finally the interval time indication disappears (Single mode).

When any scan pattern is selected in the AUTO M mode, be sure to set the interval to “0.3” or longer.

AUTO M. mode or when using Single scan pattern

The interval time can be set between 0.3 and 1.0 second.

SCAN mode

The INTERVAL button is not displayed.

Single mode

The interval time can be set between 0.05 and 1.0 second.

⑩CUSTOM button

Used to display the Custom screen to change parameters such as function settings or memory. For details, see “3.7 CUSTOM Screen (Page 39)”.

⑪Channel buttons

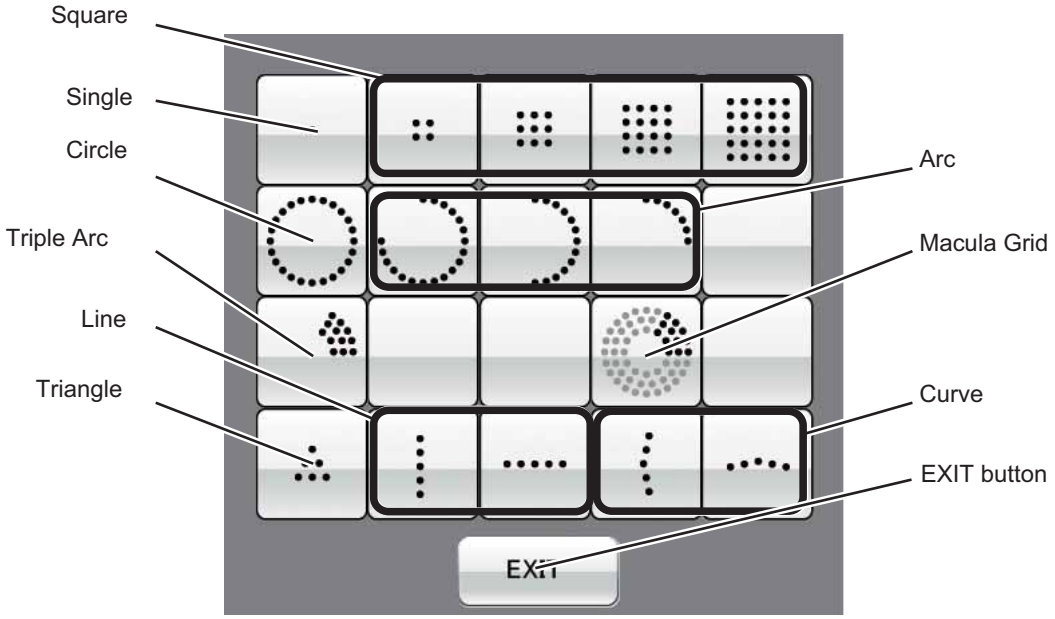
Used to toggle the channel (CH 1 or CH 2) to be used. The left button is for CH 1 to which the scan slit lamp delivery unit is connected. The right button is for CH 2 to which the BIO delivery unit is connected. An abbreviation of the connected delivery unit is displayed above each buttons as follows: “SL” (slit lamp delivery unit), “COMBO” (combination delivery unit), “BIO” (BIO delivery unit), and “ - - “ (no delivery unit connected).

⑫PATTERNS button

Pressing the PATTERNS button displays the patterns shown below. Press the desired pattern, then return to the previous screen by pressing the EXIT button.

The pattern can be selected from Single, Square (2×2, 3×3, 4×4, 5×5), Circle, Arc (3/4 circle, 1/2 circle, 1/4 circle), Triple Arc, Macula Grid, Triangle, Line, and Curve.

* The radius of the Macula Grid ranges from 100 to 200 μm.



Note

- The patterns in the screen are symbols. They do not show the actual scan pattern.

⑬Function display

Displays the function assigned to the Function button. For details of the assignable functions, see “3.7.3 Select Function screen (Page 42)”.

Function button

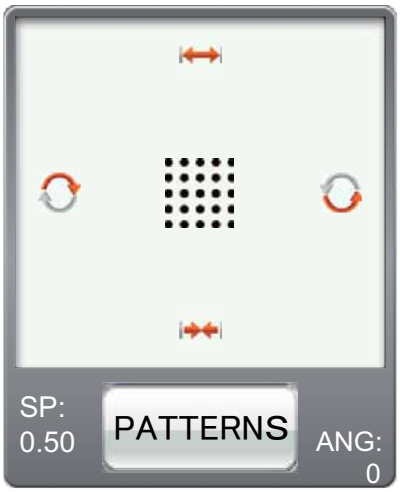
Used to execute the function assigned to the Function button.

⑭Scan pattern

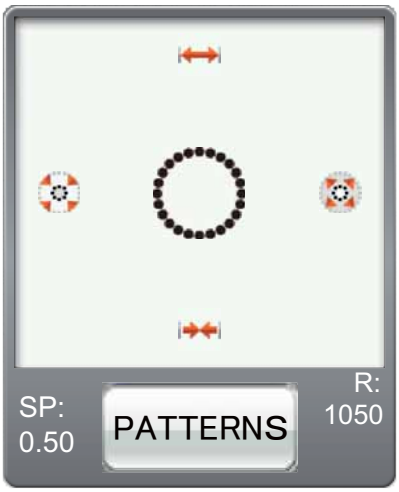
Note

- The setting range of the scan pattern may differ depending on the combination of the scan pattern, spot size, spacing, and radius.
- When the setting range of the scan pattern is changed by selecting another scan pattern, the settings such as the spacing may automatically be changed.

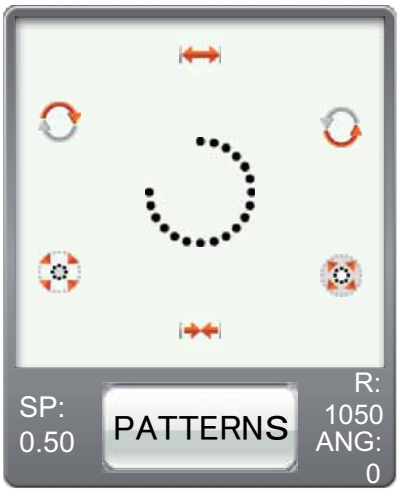
Selecting a scan pattern displays symbols above, below, and to the right and left of the scan pattern. The pattern can be modified as desired by operating these symbols.



Square



Circle



Arc or Triple Arc

Symbol	Function
	Increases the space between spots. "SP" is displayed to the left of the PATTERNS button. An indication "1.00" shows that the distances between spots are the same as the spot size.
	Reduces the space between spots.
	When the scan pattern is Circle, Arc, or Triple Arc, the radius of the circle is enlarged. "R" is displayed to the right of the PATTERNS button to show the radius of the circle (unit: μm).
	When the scan pattern is Circle, Arc, or Triple Arc, the radius of the circle is reduced.
	When the scan pattern is other than Circle, the scan pattern is rotated 15° counterclockwise. In the case of Macula Grid, the scan pattern is rotated 90° counterclockwise.
	When the scan pattern is other than Circle, the scan pattern is rotated 15° clockwise. In the case of Macula Grid, the scan pattern is rotated 90° clockwise.

⑮AIMING display and buttons

Shows the intensity of the aiming beam. There is no indication when the aiming beam is off.

AIMING buttons

The intensity of the aiming beam can be set in 15 levels. The maximum level is 15. Each time the upper button is pressed, the aiming beam becomes more intense. Each time the lower button is pressed, the aiming beam becomes less intense.

⑯Pattern memory button

For SCAN and AUTO M. modes, four most frequently used patterns can be registered.
To register patterns, display the desired pattern, then select “CUSTOM”, “Modify Memory Data”, “▼NEXT”, the desired Memory No. button, then “Exit”. For details, see “3.7.6 Modify Memory Data screen (Page 54)”.

⑰Mode buttons

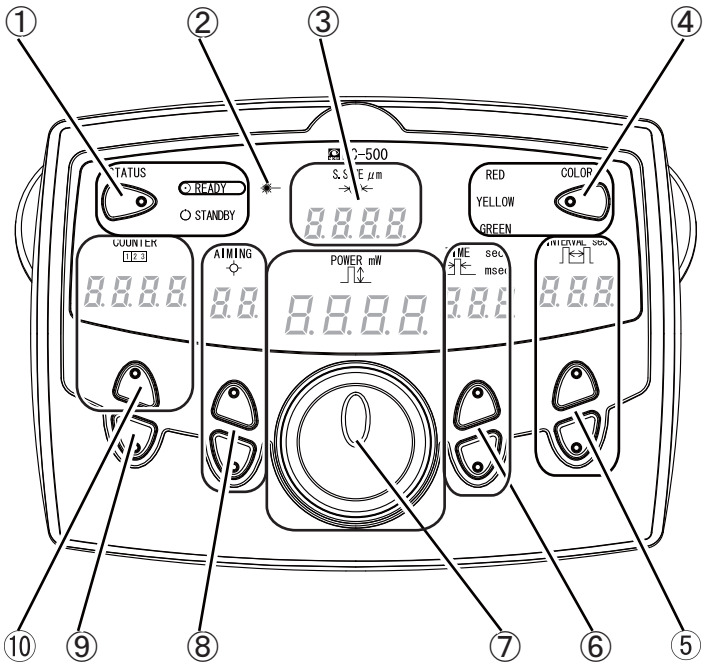
SCAN button

Scan mode
Used to perform short-time laser emission of 0.01 to 0.03 second (TIME). The interval (INTERVAL) cannot be set. There is no such limits for Single scan pattern.

AUTO M button

Auto manipulation mode
Used to perform laser emission using the desired scan pattern without limitations of the TIME and INTERVAL settings imposed in Scan mode.

3.5 Control Box (optional)



①STATUS indication and button

The treatment beam can be toggled between STANDBY and READY modes by pressing the STATUS button. When the treatment beam will not be emitted, set the system in STANDBY mode for safety.

②EMISSION indicator

Indicated while the key switch is turned ON (⊙). If any abnormality occurs to the photocoagulation system, the EMISSION indication blinks.

③SPOT SIZE display

Shows the spot diameter of the treatment beam (unit - μm) in the range from 50 to 1,000 μm. When the BIO delivery unit is used, nothing is displayed in the SPOT SIZE display of the LCD controller. In the control box, the type of the delivery unit is shown as “bio”. When the scan delivery unit is used, the range of the spot diameter of the treatment beam (unit - μm) is from 50 to 500 μm.

④COLOR indicators and button

Shows the color of the selected treatment beam.

COLOR button

Used to select the color of the treatment beam. Each time this button is pressed, the color changes as “GREEN” → “YELLOW” → “RED”... The power setting is not changed when the color is changed. However, a power larger than the maximum value for each color (GREEN 1700 mW, YELLOW 1,500 mW, RED 800 mW) cannot be set. When the scan delivery unit is used, the range of the maximum power of the GREEN treatment beam is 1,500 mW.

⑤INTERVAL display and buttons

Shows the interval time in Repeat mode (unit - second). In Single mode, there is no indication.

INTERVAL buttons

Used to toggle between the Single and Repeat modes and set the interval time in Repeat mode (unit: second). Each time the upper button is pressed, the interval time becomes longer as “no indication (Single mode)” → “0.05” → “0.10”...”1.0.” Each time the lower button is pressed, the interval time becomes shorter and finally the interval time indication disappears (Single mode). When the scan delivery unit is used in SCAN mode, there is no indication.

⑥TIME display and buttons

Shows the treatment beam emission time (unit - second).

If the operating procedure for projection of the aiming laser beam or operation of the treatment beam is improper, an abbreviated error indication is indicated in the control box. For details, see “8.2 Indications of Misoperation (Page 97)”.

TIME buttons

Used to set the treatment beam emission time (unit - second).
Each time the upper button is pressed, the emission time becomes longer. Each time the lower button is pressed, the interval time becomes shorter. The emission time changes in increments of 0.01 second between 0.01 and 0.10 second, in increments of 0.05 second between 0.10 and 0.50 second, in increments of 0.10 second between 0.50 and 1.00 second, and in increments of 1.00 second between 1.00 and 3.00 seconds. When the scan delivery unit is used, the emission time changes in increments of 0.01 second between 0.01 and 0.03 second (except for Single mode).

⑦ POWER display and buttons

Shows the power output of the treatment beam (on the cornea) (unit - mW). The maximum power output differs depending on the color of the treatment beam.

POWER control

Used to set the power output of the treatment beam (on the cornea) (unit - mW).
When the POWER control is turned, the power output can be set in increments of 10mW between 50 and 500mW, and in increments of 50 mW in the higher range. When the POWER control is turned while it is pressed, the power output can be set in increments of 100 mW.

⑧AIMING display and buttons

Shows the intensity of the aiming beam. There is no indication when the aiming beam is off.

AIMING buttons

The intensity of the aiming beam can be set in 15 levels. The maximum level is 15. Each time the upper button is pressed, the aiming beam becomes more intense. Each time the lower button is pressed, the aiming beam becomes less intense.

⑨Function button

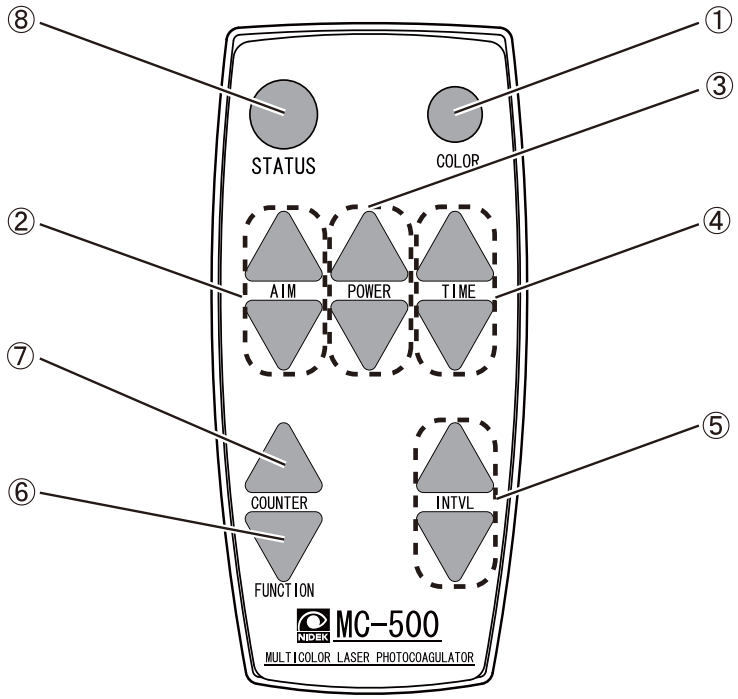
Used to toggle use of Repeat mode. The function of this button is the same as that in the middle of the INTERVAL buttons on the LCD screen.

⑩COUNTER RESET button

Pressing this button returns the counter to “0” (zero).

The number of the treatment laser beam emission is displayed to the right of this button in the range of 0 to 9999.

3.6 Remote Control (optional)



①COLOR button

Used to select the color of the treatment beam. Each time this button is pressed, the color changes as "GREEN" → "YELLOW" → "RED"... The power setting is not changed when the color is changed. However, a power larger than the maximum value for each color (GREEN 1,700 mW, YELLOW 1,500 mW, RED 800 mW) cannot be set. When the scan slit lamp delivery unit is used, the range of the maximum power of the GREEN treatment beam is 1,500 mW.

②AIMING buttons

The intensity of the aiming beam can be set in 15 levels. The maximum level is 15. Each time the upper button is pressed, the aiming beam becomes more intense. Each time the lower button is pressed, the aiming beam becomes less intense.

③POWER button

Used to set the power output of the treatment beam (on the cornea) (unit - mW). Pressing the upper button increases the power output, and pressing the lower button decreases it in increments of 10mW between 50 and 500mW, and in increments of 50 mW in the higher range.

④TIME buttons

Used to set the treatment beam emission time (unit - second).

Each time the upper button is pressed, the emission time becomes longer. Each time the lower button is pressed, the interval time becomes shorter. The emission time changes in increments of 0.01 second between 0.01 and 0.10 second, in increments of 0.05 second between 0.10 and 0.50 second, in increments of 0.10 second between 0.50 and 1.00 second, and in increments of 1.00 second between 1.00 and 3.00 seconds. When the scan delivery unit is used in SCAN mode, the emission time changes in increments of 0.01 second between 0.01 and 0.03 second (except for Single mode).

⑤INTERVAL buttons

Used to toggle between the Single and Repeat modes and set the interval time in Repeat mode (unit: second). Each time the upper button is pressed, the interval time becomes longer as “no indication (Single mode)” → “0.05” → “0.10”...”1.0.” Each time the lower button is pressed, the interval time becomes shorter and finally the interval time indication disappears (Single mode).

⑥Function button

Used to toggle use of Repeat mode. The function of this button is the same as that in the middle of the INTERVAL buttons on the LCD screen. To enable this function, see “3.7.3 Select Function screen (Page 42)” and select “Interinterval On/Off”.

⑦ COUNTER RESET button

Pressing this button returns the counter to “0” (zero).

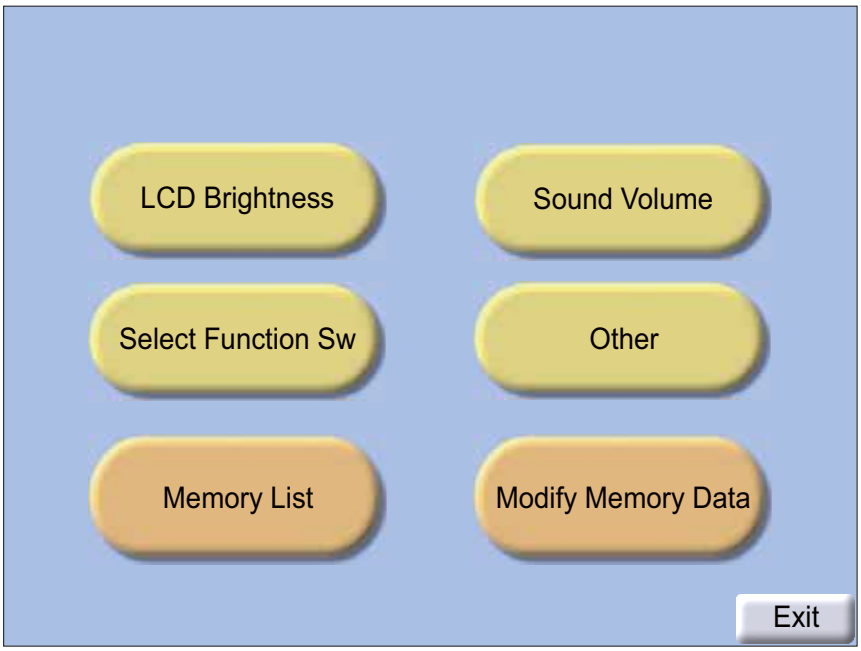
The number of the treatment laser beam emission is displayed to the right of this button in the range of 0 to 9999.

⑧STATUS button

The treatment beam can be toggled between STANDBY and READY modes by pressing the STATUS button. When the treatment beam will not be used, set the system in STANDBY mode for safety.

3.7 CUSTOM Screen

The CUSTOM screen is displayed by pressing the CUSTOM button in the Main screen.



LCD Brightness button

Used to display the LCD Brightness Setting screen. For details, see “3.7.1 LCD Brightness screen (Page 40)”.

Sound Volume button

Used to display the Sound Volume Setting screen. For details, see “3.7.2 Sound Volume screen (Page 41)”.

Select Function Sw button

Used to display the Select Function screen. For details, see “3.7.3 Select Function screen (Page 42)”.

Other button

Used to display the Other Setting screen. For details, see “3.7.4 Other Setting screen (Page 43)”.

Memory List button

Used to display the Memory List screen. For details, see “3.7.5 Memory List screen (Page 53)”.

Modify Memory Data button

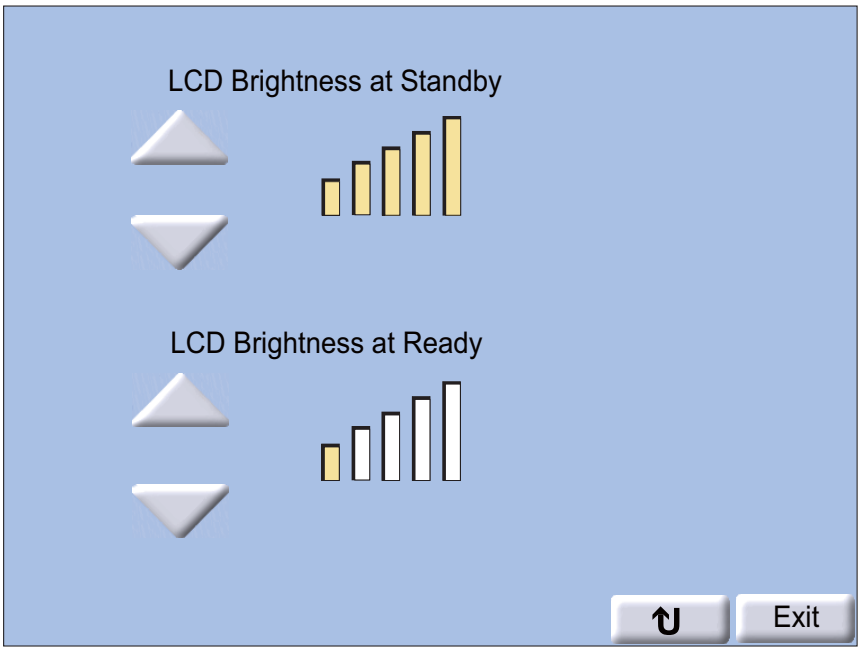
Used to display the Modify Memory Data screen. For details, see “3.7.6 Modify Memory Data screen (Page 54)”.

EXIT button

Used to exit the CUSTOM screen.

3.7.1 LCD Brightness screen

In this screen, the brightness of the LCD controller in STANDBY and READY modes can be set.



LCD Brightness at Standby

The brightness of the LCD controller in STANDBY mode can be adjusted by pressing the and buttons. The level of brightness is displayed by the amount of area colored yellow along the scale.

LCD Brightness at Ready

The brightness of the LCD controller in READY mode can be adjusted by pressing the and buttons. The level of brightness is displayed by the amount of area colored yellow along the scale.

Return button

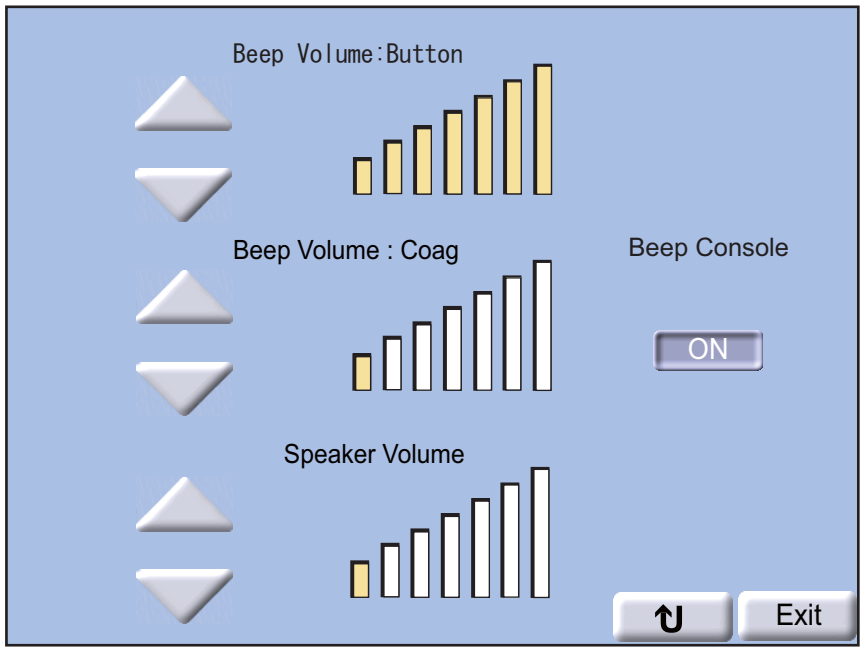
Used to return to the initial CUSTOM screen.

Exit button

Used to return to the Main screen.

3.7.2 Sound Volume screen

In this screen, the volume of various sounds produced by the device can be set.



Beep Volume : Button

The volume of the sound produced when the buttons on the control box are pressed can be adjusted by pressing the and buttons. The sound volume is displayed by the amount of area colored yellow along the scale.

Beep Volume : Coag

The volume of the sound produced from the control box during the laser emission can be adjusted by pressing the and buttons. The sound volume is displayed by the amount of area colored yellow along the scale.

Beep Console: Set this parameter to “ON” to sound a beep when emitting the treatment laser beam. Set it to “OFF” when the optional control box is used.

Speaker Volume

The voice guidance can be toggled by pressing the and buttons. The sound volume is displayed by the amount of area colored yellow along the scale.

Return button

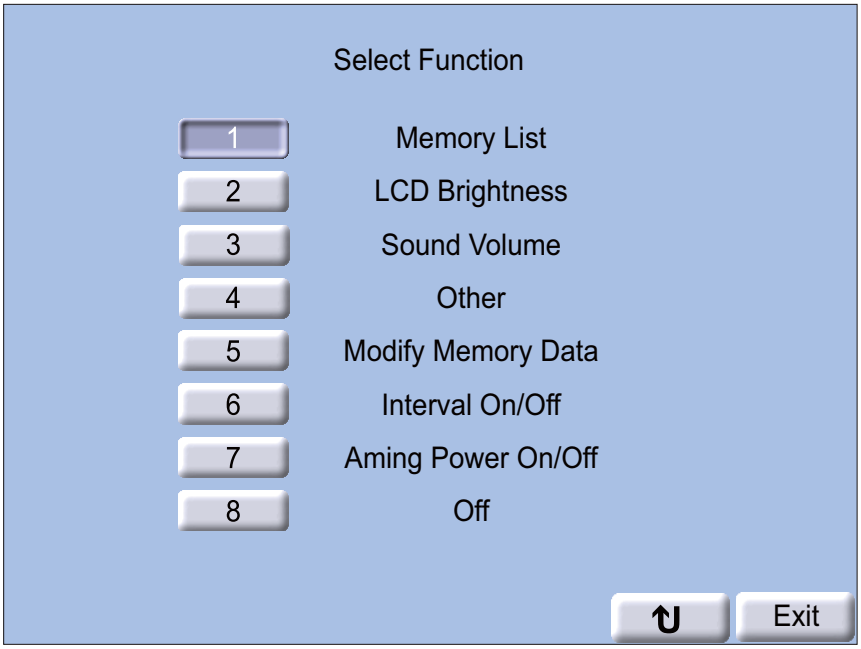
Used to return to the initial CUSTOM screen.

Exit button

Used to return to the Main screen.

3.7.3 Select Function screen

This screen allows the operator to assign the desired function to the Function button.



1. Memory List
Displays the Memory List screen. For details, see “3.7.5 Memory List screen (Page 53)”.

2. LCD Brightness
Displays the LCD Brightness Setting screen. For details, see “3.7.1 LCD Brightness screen (Page 40)”.

3. Sound Volume
Displays the Sound Volume Setting screen. For details, see “3.7.2 Sound Volume screen (Page 41)”.

4. Other
Displays the Other Settings screen. For details, see “3.7.4 Other Setting screen (Page 43)”.

5. Modify Memory Data
Displays the Modify Memory Data screen. For details, see “3.7.6 Modify Memory Data screen (Page 54)”.

6. Interval On/Off
Toggles between the Single mode and Repeat mode with the set interval. The function is the same as the middle INTERVAL button in the LCD controller.

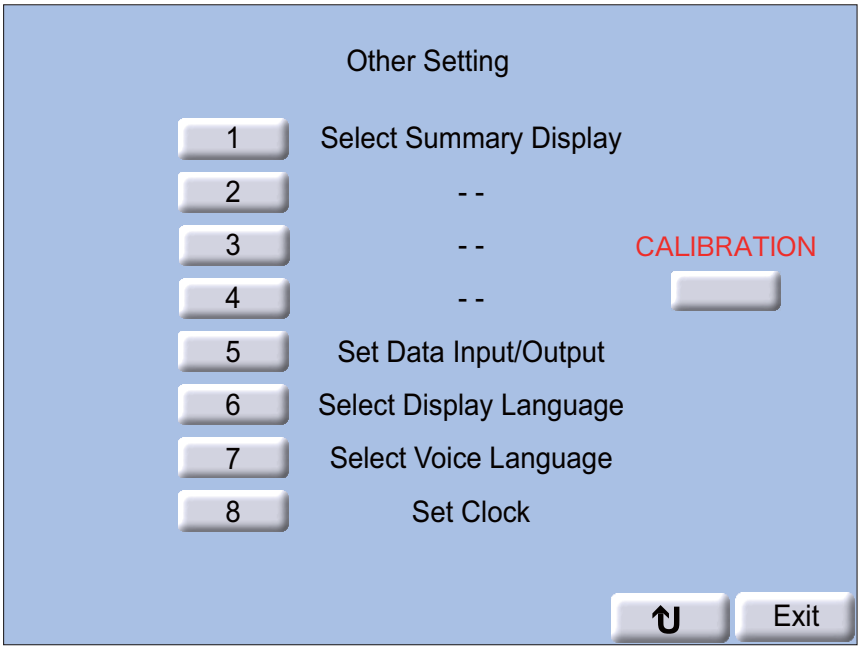
7. Aiming Power On/Off
Turns ON and OFF the aiming beam. The function is the same as the middle AIMING button in the LCD controller.

8. Off
When this button is highlighted, no function is assigned to the Function button.

Return button
Used to return to the initial CUSTOM screen.

Exit button
Used to return to the Main screen.

3.7.4 Other Setting screen



1. Select Summary Display

Used to display the Select Summary Display screen. For details, see “3.7.4.1 Select Summary Display screen (Page 44)”.

5. Set Data Input/Output

Used to display the screen for setting parameters of the LAN or such. For details, see “3.7.4.2 Set Data Input/Output screen (Page 47)”.

6. Select Display Language

Used to display the Select Display Language screen. For details, see “3.7.4.3 Select Display Language screen (Page 50)”.

7. Select Voice Language

Used to display the Select Voice Language screen. For details, see “3.7.4.4 Select Voice Language screen (Page 51)”.

8. Set Clock

Used to display the Set Clock screen. For details, see “3.7.4.5 Adjust Clock screen (Page 52)”.

CALIBRATION

Used to calibrate laser power output. Entering Calibration mode requires a password. For details of the calibration, see “6.4 Calibrating Laser Power Output (Treatment and Aiming Beams) (Page 77)”.

Return button

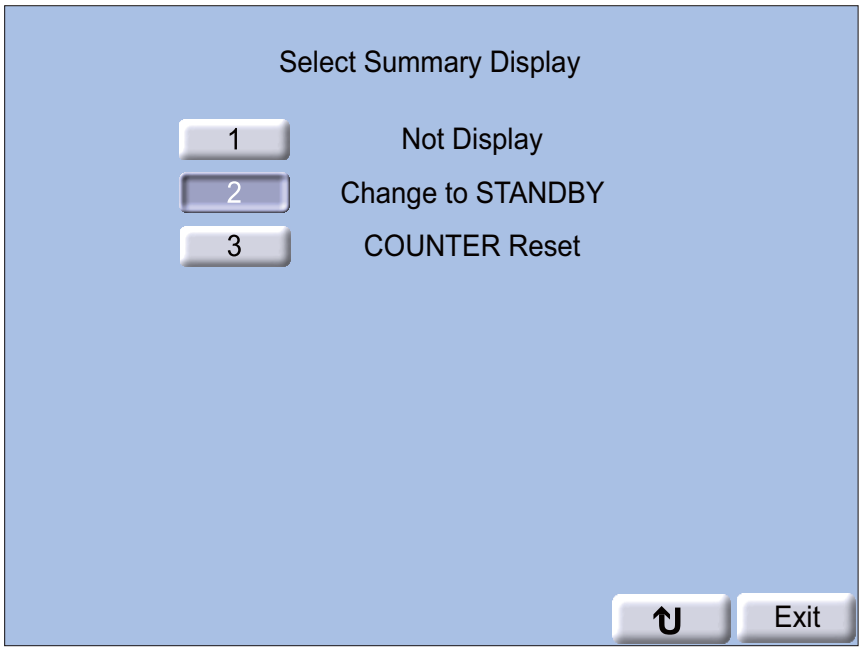
Used to return to the initial CUSTOM screen.

Exit button

Used to return to the Main screen.

3.7.4.1 Select Summary Display screen

This screen allows the operator to set the condition to display the summary of treatment*.
(* See the next page for details of the summary treatment.)



Press to highlight the button shown to the left of the desired condition to display the summary of treatment.

1. Not Display
The summary of treatment is not displayed.

2. Change to STANDBY
The summary of treatment is displayed when the device is switched from the READY to STANDBY mode with the STATUS button.

3. COUNTER Reset
The summary of treatment is displayed when the COUNTER is reset with the COUNTER reset button.

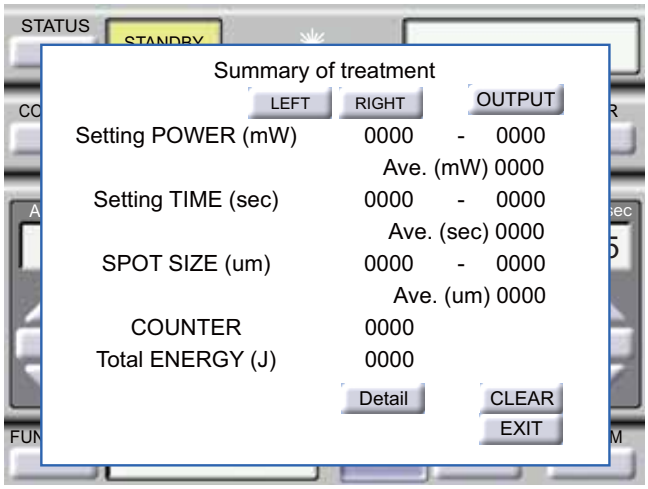
Return button
Used to return to the initial CUSTOM screen.

Exit button
Used to return to the Main screen.

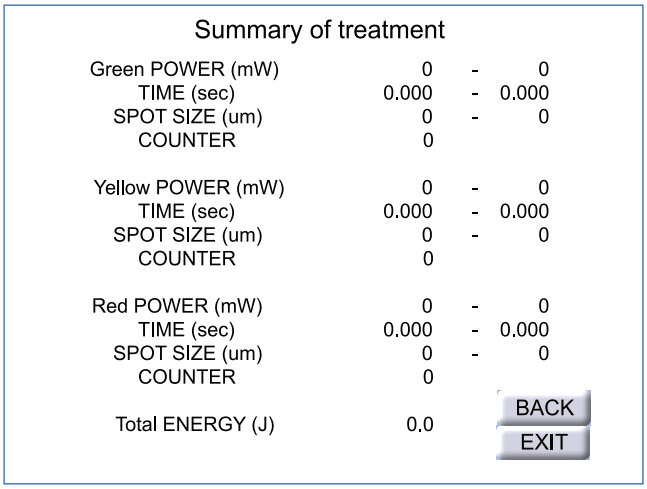
⚠ **CAUTION** • **When "Change to STANDBY" or "COUNTER Reset" is selected in the Select Summary Display screen, be sure to press the COUNTER RESET button to reset the counter before executing laser emission.**

The summary of treatment shows various information on the laser emission that has been executed as shown below.

<Summary of treatment screen>



<Detailed Summary of treatment screen>



The Summary of treatment screen appears according to the condition specified in the Select Summary Display screen.

Detail button

Used to display the detailed Summary of treatment screen.

CLEAR button

Used to reset the values in the Summary of treatment or Detailed summary of treatment screen to “0000”.

LEFT button

Used when the treatment data is for the left eye. For the treatment data for both eyes, the RIGHT button can be pressed at the same time.

This button is displayed when “LAN” is selected for the “Set Data Output” parameter in the Set Data Input/Output screen.

RIGHT button

Used when the treatment data is for the right eye. For the treatment data for both eyes, the LEFT button can be pressed at the same time.

This button is displayed when “LAN” is selected for the “Set Data Output” parameter in the Set Data Input/Output screen.

OUTPUT button

Used to output treatment data according to the “Set Data Output” parameter (LAN or such) selected in the Set Data Input/Output screen.

BACK button

Used to return to the Summary of treatment screen.

EXIT button

Used to return to the Main screen. When the EXIT button is pressed, the values in the Summary of treatment or Detailed summary of treatment screen are cleared.

Note

- When “COUNTER Reset” is selected for the condition to display the Summary of treatment screen, values in the screen become “0000” as in the case where the CLEAR button is pressed even when the EXIT button is pressed because the counter is reset.
- In the Summary of treatment screen, “Total ENERGY (J)” may not correspond with POWER multiplied by TIME due to the number of digits that can be displayed.

3.7.4.2 Set Data Input/Output screen

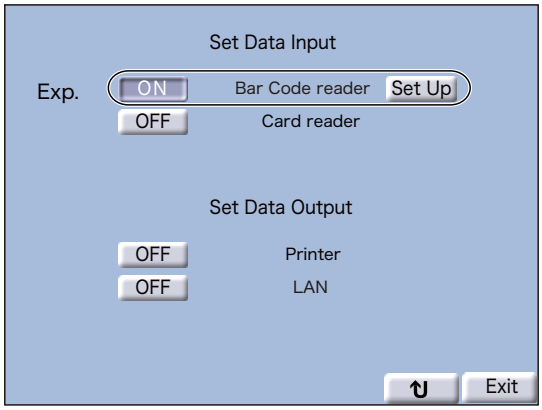
Set Data Input

This screen allows the operator to toggle between the barcode reader or the card reader.

Patient IDs read with the barcode reader or the card reader can be displayed in the message display of the LCD controller.

1 **Press the button of the desired reader.**

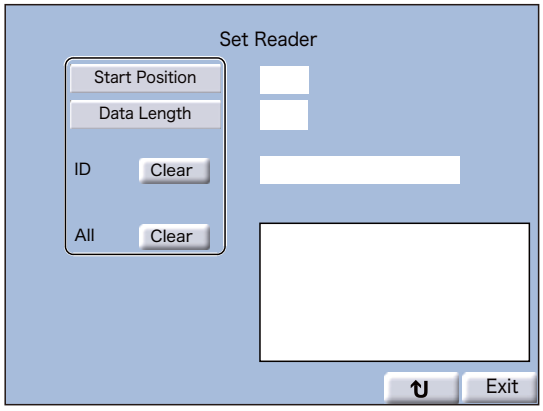
The Set Up button appears for the selected reader.



2 **Press the Set Up button.**

3 **The Set Reader screen is displayed.**

Pressing the Start Position or Data Length button displays a numerical keypad. Input the start position and the number of digits to be read.



Start position: (1 to 50 digits)

Specify the position of the first digits for ID.

Number of digits: (1 to 14 digits)

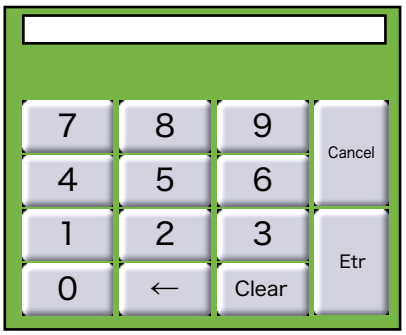
Specify the number of digits for ID to be read from the start position.

ID:

An ID specified with the start position and the number of digits is displayed.

All:

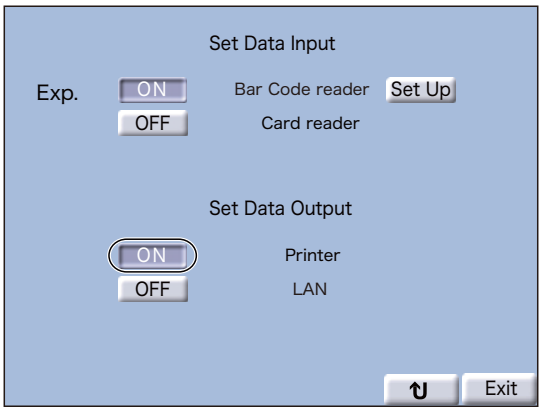
All the read data pieces are displayed. Parts specified as an ID are displayed in red.



Setting for outputting data

○ Printer setting

1) Press the Printer button.

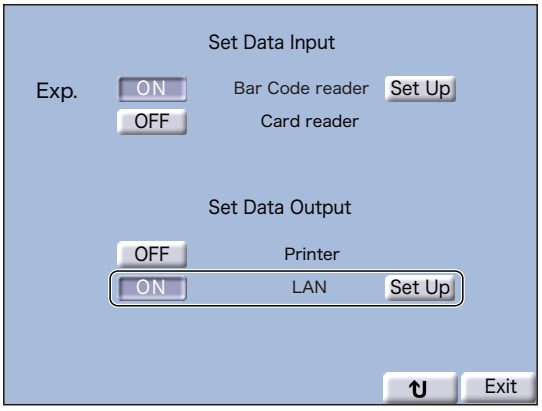


○ LAN setting

Note

- NIDEK service personnel will perform the connection and setting with permission from a network administrator of each facility.
- Before connecting the main body to the network, confirm the following points with the network administrator of the facility:
  1. The DHCP can be turned on.
  2. TCP/IP...IP address and subnet mask of the main body
  3. File sharing of computer...Use name, password, and domain
  4. Name and setting of the folder to which measurement data is to be saved.
- After changing the network function setting, return to the measurement screen, then restart the main body (power off and on).
  The setting change becomes effective when the main body is restarted.

1) Press the LAN button.
2) Press the Set Up button.

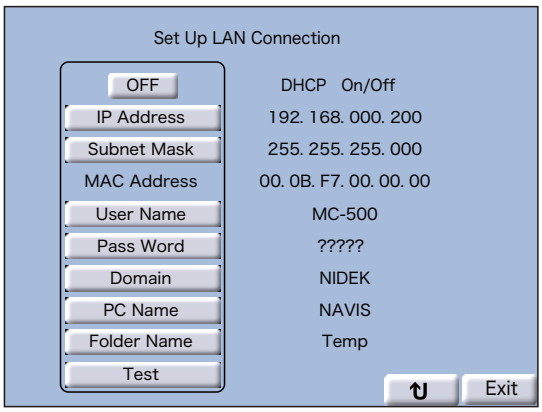


3) The “Set Up LAN Connection” screen is displayed.

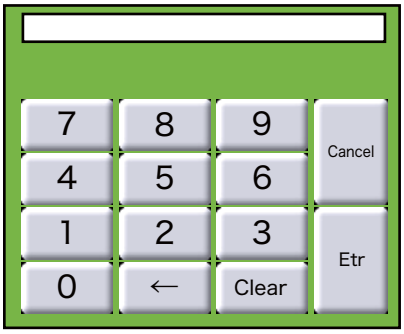
4) Press the buttons in the screen and input the parameters.

   The password is displayed with question marks (?).

   Pressing the user name or the folder name button displays a keyboard. Input alphabetical characters.

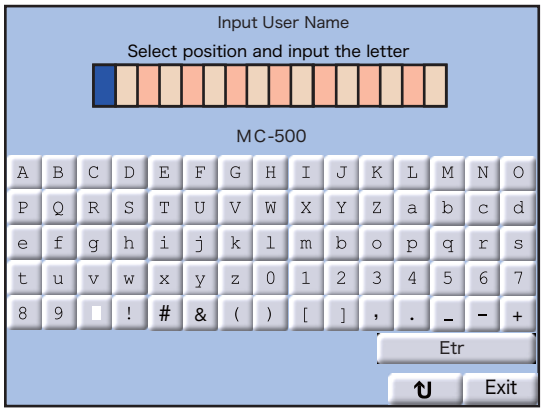


5) Pressing the IP address or the subnet mask button displays a numerical keypad. Input numerical characters.

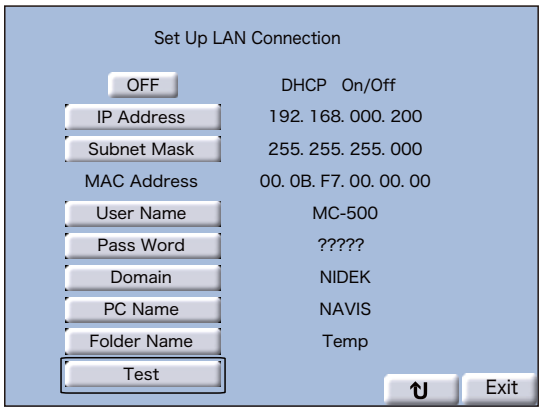


6) Pressing the user name, password, domain, computer name, or folder name button displays a keyboard. Input alphabetical characters.

   Although the password is input with alphabetical characters, they are displayed as question marks (?) in the “Set Up LAN Connection” screen.



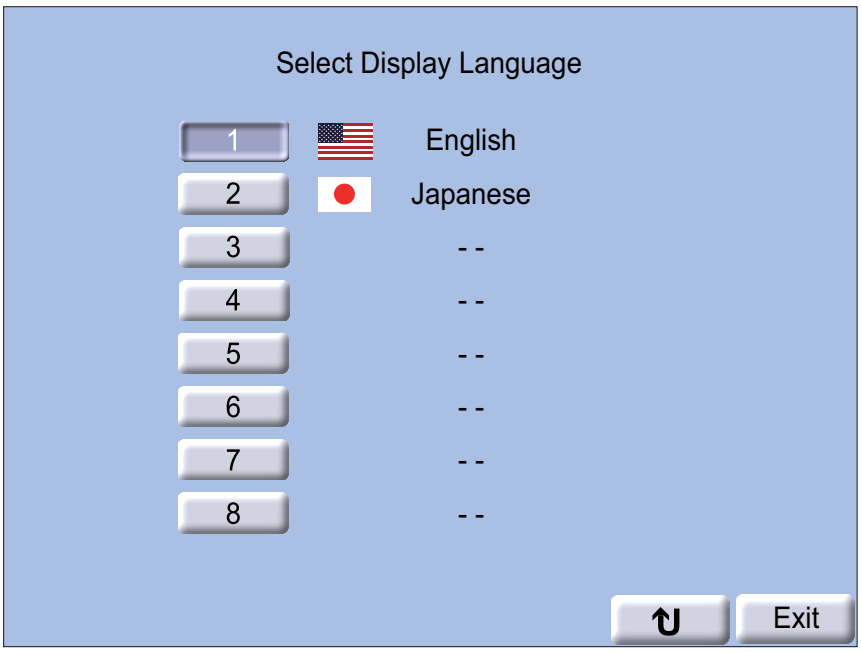
7) After the setting is complete, perform the procedure of “3.8.1 Network connection (LAN) (Page 56)”, then press the Test button to check the connection.



3.7.4.3 Select Display Language screen

This screen allows the operator to select the desired display language.

Press to highlight the button shown to the left of the desired display language.



Return button 

Used to return to the initial CUSTOM screen.

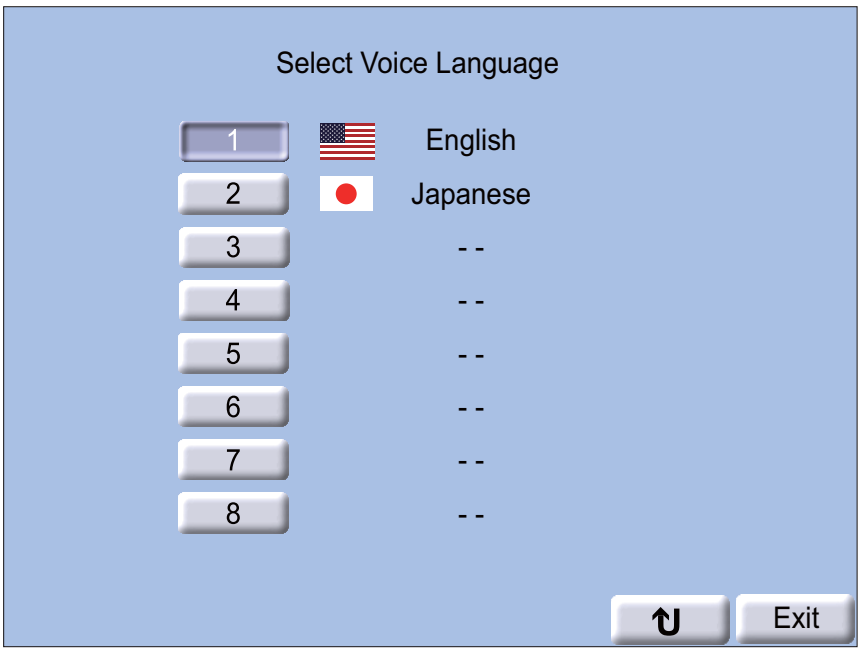
Exit button

Used to return to the Main screen.

3.7.4.4 Select Voice Language screen

This screen allows the operator to select the desired voice guidance language.

Press to highlight the button shown to the left of the desired voice guidance language.



Return button 

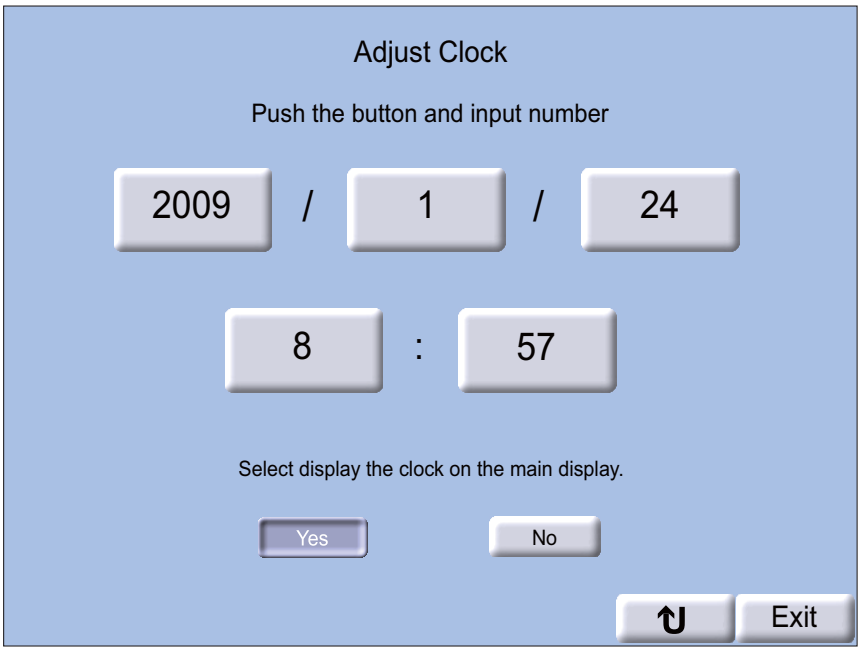
Used to return to the initial CUSTOM screen.

Exit button

Used to return to the Main screen.

3.7.4.5 Adjust Clock screen

This screen allows the operator to set the clock and toggle display of the clock in the Main screen.



Push the button and input number

The three buttons in the upper row represent year, month, and day from the left to right. The two buttons in the middle row represent hour and minute. When these buttons are pressed, a numeric keypad screen appears. Input the desired value, then press the Enter button in the numeric keypad screen.

Select display of the clock on the main display.

Press to highlight the desired button.

Yes - The clock is displayed in the Main screen.

No- The clock is not displayed in the Main screen.

Return button 

Used to return to the initial CUSTOM screen.

Exit button

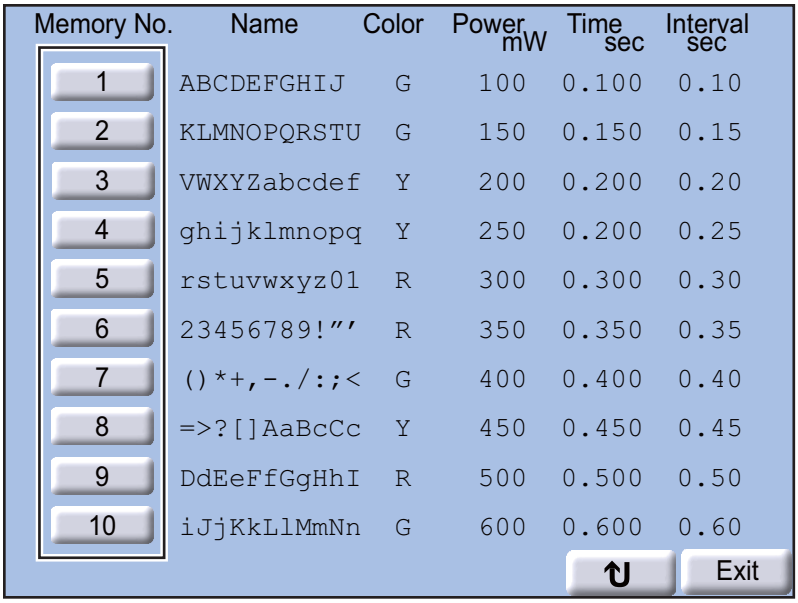
Used to return to the Main screen.

Note

- If the main body has not been used for more than a month, the date and time may be shifted. In such a case, set them again and keep power to the main body on for more than 20 minutes.

3.7.5 Memory List screen

This screen allows the operator to view and call up the desired treatment beam setting data stored in the device.



Memory No. buttons

Press the button shown to the left of the desired treatment beam setting data to call up.

Return button 

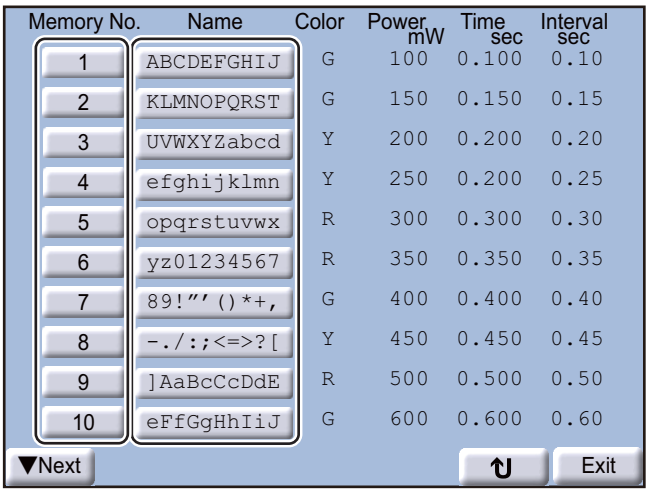
Used to return to the initial CUSTOM screen.

Exit button

Used to return to the Main screen.

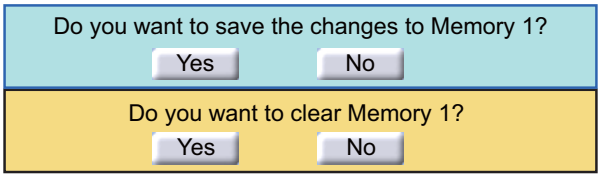
3.7.6 Modify Memory Data screen

This screen allows the operator to save or modify the treatment beam setting data.



Memory No. buttons

Used to save or delete the treatment beam setting data. When the desired button is pressed, the dialog boxes shown to the right appear. To save the current treatment beam setting with the selected Memory No., press “Yes” in the upper dialog box. If the selected Memory No. is used for an existing treatment beam setting data set, the existing treatment beam setting data set is overwritten with the new one. To delete the existing treatment beam setting data set without saving the current one, press “Yes” in the lower dialog box. To not save the current treatment beam setting data set or delete the existing one, press “No” in either dialog box.

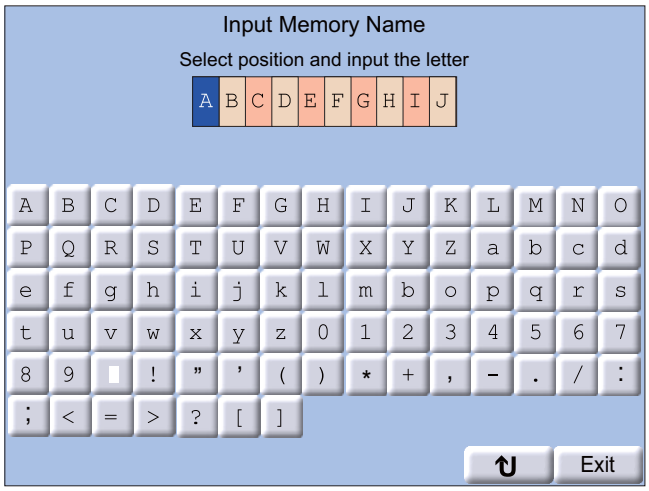


Name buttons

Used to change the names of treatment beam setting data sets. When the desired buttons is pressed, the Input Memory Name screen shown to the right appears.

Press to highlight the desired place of the ten boxes at the top of the screen, then input the desired character with the keypad.

When the input of the name is completed, press the Return or Exit button.



Return button 

Used to return to the initial CUSTOM screen.

Exit button

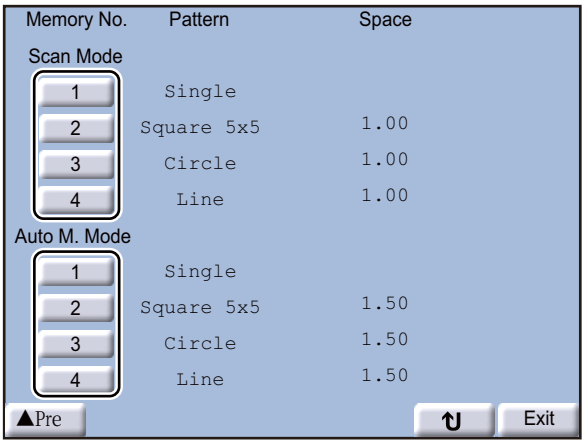
Used to return to the Main screen.

Next button

Used to display the screen below in which scan patterns can be saved or deleted.

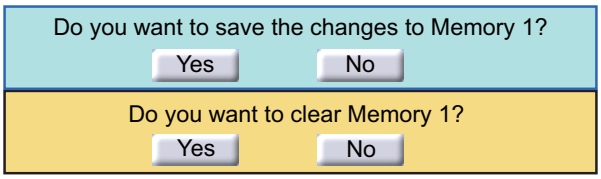
Pre button

Used to display the screen in which treatment data can be saved or changed.



Memory No. buttons

Used to save or delete the scan pattern. When the desired Memory No. button is pressed, the dialog boxes shown to the right appears. To save the currently used scan pattern to the selected Memory No., press “Yes” in the upper dialog box. If the selected Memory No. is used for an existing scan pattern, the existing scan pattern is overwritten with the new one. To delete the existing scan pattern without saving the current one, press “Yes” in the lower dialog box. To not save the currently used scan pattern or delete the existing one, press “No” in either dialog box.



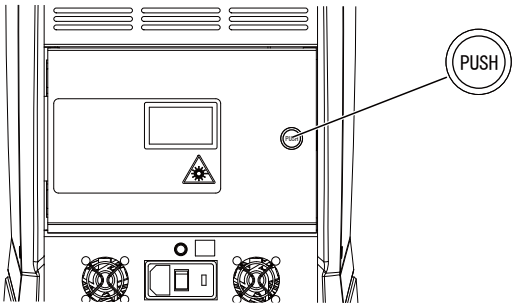
3.8 Connecting Optional Accessories

The MC-500 can output data to the NIDEK NAVIS software as an external device.

⚠ **CAUTION** • **Before connecting cables, be sure to turn off power to the devices to be connected with the cables.**
The devices may fail.

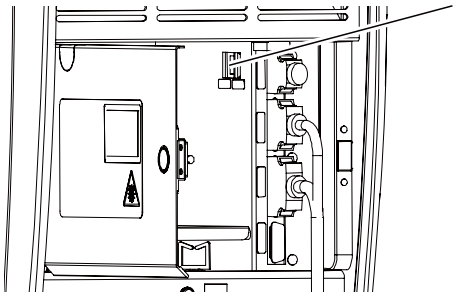
3.8.1 Network connection (LAN)

1 Press the rear cover button on the back of the main body to open the rear cover.

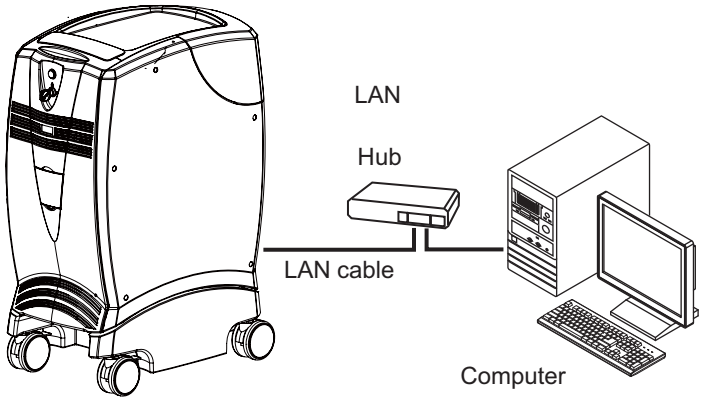


2 Connect a LAN cable to the LAN connector on the place where the foot switch is stored. Then close the rear cover.

LAN connector



3 Connect the LAN cable to the network (hub) to which the computer is connected.



Note

- Be sure to connect the main body with a PC through a network hub.
  Never connect the main body directly to a PC. A connection failure may occur.

4 Set the necessary parameters.

After receiving permission from the network administrator of the facility, set the parameters for the main body and the computer.

1) Set the LAN parameters for the main body.

   See “○LAN setting (Page 48)”.

2) Set the parameter for displaying the summary of treatment. (Method of patient data transfer)

   See “3.7.4.1 Select Summary Display screen (Page 44)”.

Entrust the connection to NIDEK service personnel.

3.8.2 Connecting barcode reader / magnetic card reader

Turn off power to the main body, then connect the barcode reader or the magnetic card reader to the USB-A connector on the back of the main body.

⚠ **CAUTION**

- **Do not connect or disconnect the barcode reader or the magnetic card reader with power to the main body on.**
  An error may result.

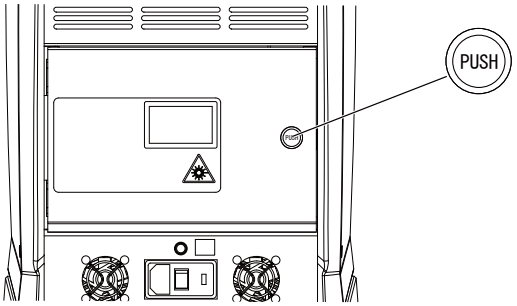
Note

- Only the specific barcode reader or the magnetic card reader (optional) can be used.

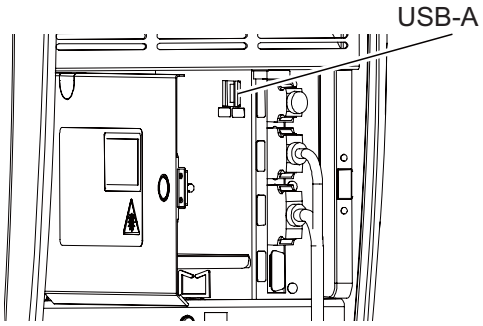
The barcode reader / magnetic card reader is connected to the USB-A connector on the back of the main body.

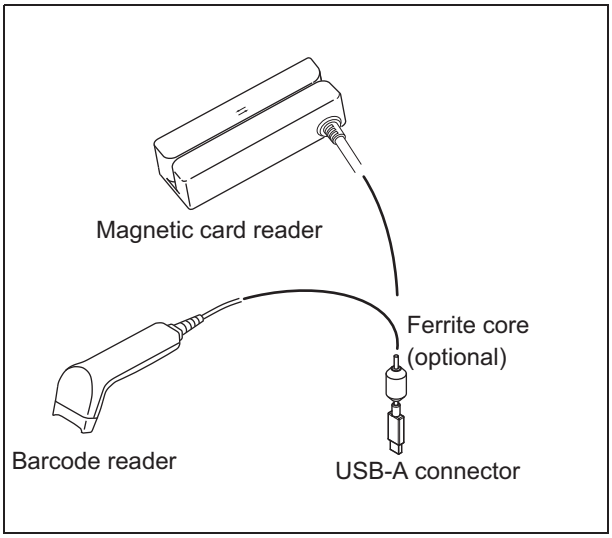
Attach the ferrite core (optional) to the end of the cable which is connected to the main body.

1 Press the rear cover button to open the rear cover.



2 Connect the USB connector of the barcode reader / magnetic card reader to the USB-A connector on the back of the main body. Then close the rear cover.





Note

- Turning on power to the device with the barcode reader / magnetic card reader connected to the main body sounds a beep.

  The beep is for confirmation of the connection. It does not indicate any abnormality.

3.9 Reading Patient ID

Patient IDs can be read using barcodes or magnetic cards. Patient IDs read from them are used in the NIDEK NAVIS software.

Note

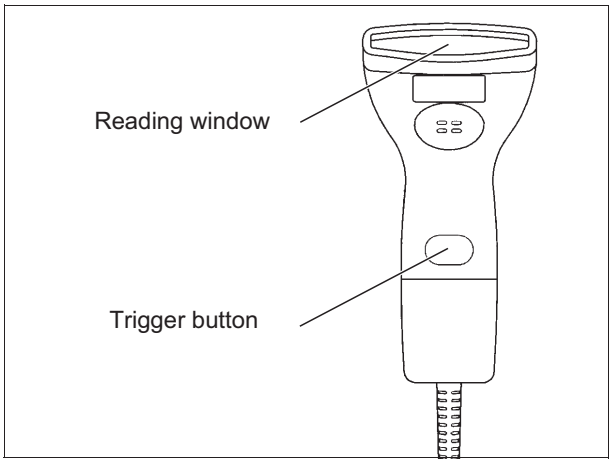
- Although patient IDs can be read post- or preoperatively, be sure to read the patient ID before transferring the summary of treatment.

  If a patient ID is read while a summary of treatment that has been transferred is displayed, the main body regard the summary as the one for the previous patient and automatically deletes it.
- The most recently input patient ID that has not been transferred is regarded as the patient ID.

  If an improper patient ID has been read, read the proper patient ID again.

1 Read with the barcode reader. (For the magnetic card reader, go to 2).)

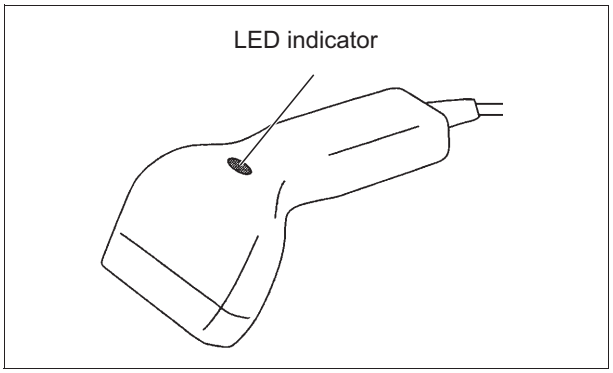
1) Aim the reading window at the barcode.



2) Press the trigger button.

   The reading window illuminates in red and the barcode is read.

   When reading of the barcode is finished, the LED indicator illuminates and a beep is heard.



Note

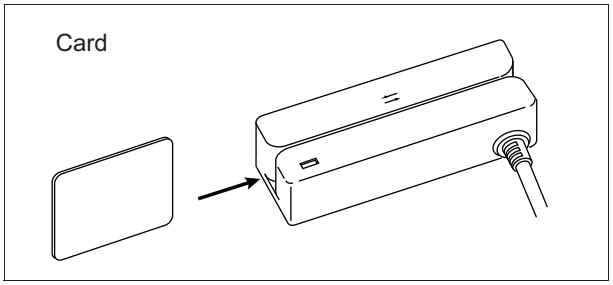
- For the barcode, use CODE 39.
- For the patient ID, numerical and alphabetical characters and signs “_” and “-” can be used.

  Other characters or signs cannot be acknowledged and become converted to “ ~ “ .

2 Read with the magnetic card reader.

1) Slide the card through the magnetic card reader.

   A beep sounds and the green LED turns off. When reading of the card is finished, the green LED illuminates again.



Note

- Use magnetic cards in the magnetic stripe formats of ISO 7811, AAMVA, CA DMV.
- For the patient ID, numerical and alphabetical characters and signs "_" and "-" can be used.
  Other characters or signs cannot be acknowledged and become converted to " ~ " .

Usable barcode reader / magnetic card reader

Barcode reader

NAV-3 (NAVIS-CL) **19701-E006**	USB barcode reader (OPL-5850-USB manufactured by ROLAN)
NAV-2 (NAVIS-HP) **36120-E122**	USB barcode reader (USBee-1000 manufactured by Welcom Design)

Magnetic card reader

US10OP-1 (US-4000 optional) **14631-E001**	Magnetic stripe card reader (MS240-2U MSR track I, II manufactured by Unitec Japan)

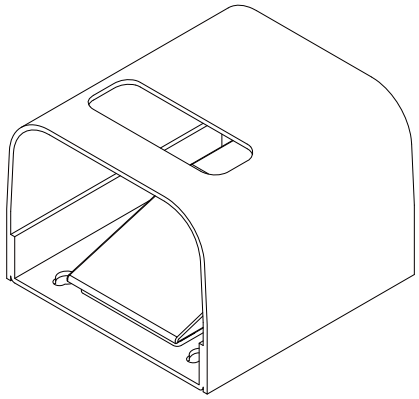
The magnetic card reader (19701-E003: PDC-816-050-U5) specified for NAVIS-CL, and the magnetic card reader (36120-E121: FT-900U-1R-0101) specified for NAVIS-HP cannot be used. Although they can be connected, IDs cannot be read.

3 When patient ID is read, the patient ID appears in the message display in the LCD controller of the main body.

4 Postoperatively, press the COUNTER RESET button or the STANDBY button in the LCD controller to transfer the patient ID and the summary of treatment. (For details of button setting, see “3.7.4.1 Select Summary Display screen (Page 44)”.)

5 When data transfer is complete, a message appears.

3.10 Foot Switch



4. PHOTOCOAGULATION

⚠ **CAUTION** • **This section provides cautions for use of the MC-500 to perform photocoagulation, treatment parameters for applications as only a guide. As applications are at the physician's discretion, NIDEK is not responsible for the applications.**

The safety and efficacy of laser photocoagulation have been documented in a number of medical literatures since the clinical use started in 1968, and the laser photocoagulation has been applied to various pathologies.
The MC-500 is the instrument that the wavelength can be selected for laser photocoagulation in ophthalmology: red (wavelength: 647 nm), yellow (wavelength: 577 nm), and green (wavelength: 532 nm). Laser photocoagulation by using the MC-500 can be applied to treat the following pathologies:

- •Diabetic retinopathy
- •Choroidal neovascularization
- •Branch retinal vein occlusion
- •Age-related macular degeneration
- •Acute angle closure glaucoma
- •Chronic open angle glaucoma
- •Retinal tears
- •Retinopathy of prematurity

4.1 Characteristics of Laser

4.1.1 General characteristics of laser

1. Laser of longer wavelength increases the penetration depth of light in tissues.
2. Lasers of all wavelengths are highly absorbed by melanin in the retinal pigment epithelium and choroid.
3. Laser which has a complementary color of the pigment in tissue is highly absorbed.
   [Example 1]
   Green wavelength which is a complementary color of red in tissue is highly absorbed than yellow wavelength in blood. Longer wavelength than orange is highly penetrated.
   [Example 2]
   Blue wavelength which is a complementary color of yellow is highly absorbed by xanthophyll. Green wavelength increases the penetration depth, and longer wavelength than yellow almost penetrates tissue.
4. Long wavelength which has high penetration is much effective to treat the opaque ocular media.
5. Treatment with long wavelength (red) is attended with pain since the laser passes on the choroid.
6. Red wavelength needs much higher power than the other wavelengths to obtain the coagulation macular on retina.

4.1.2 Characteristics of wavelength

(a) Red wavelength

- Highly absorbed by melanin in retinal pigment epithelium or choroid.
- Lowly absorbed by hemoglobin. Laser beam is rarely scattered in intraocular transit.
- Negligibly absorbed by xanthophyll in macula. This minimizes undesired inner retinal damage during macular photocoagulation.

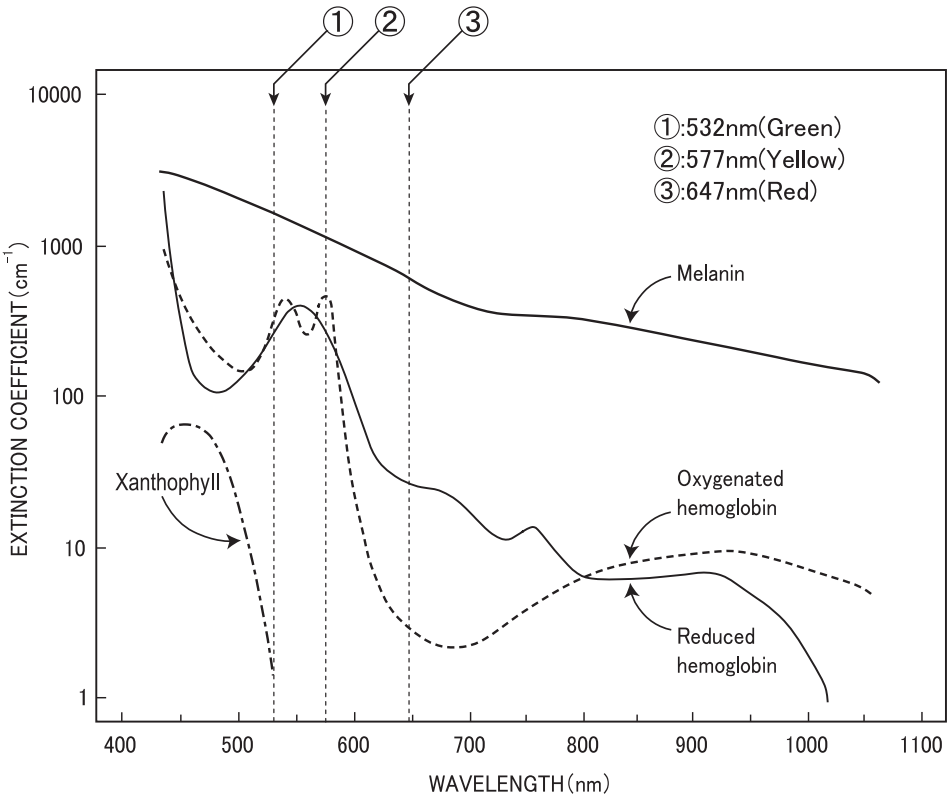
(b) Yellow wavelength

- Highly absorbed by melanin in retinal pigment epithelium or choroid. This decreases the penetration depth and reduces a pain in retinal photocoagulation.
- Highly absorbed by hemoglobin. The wavelength 561 nm is highly absorbed by reduced hemoglobin than oxygenated hemoglobin. This is effective to photocoagulate vessels which contains high hemoglobin.
- Negligibly absorbed by xanthophyll in macula. This minimizes undesired inner retinal damage during macular photocoagulation.

(c) Green wavelength

- Highly absorbed by melanin in retinal pigment epithelium or choroid. This decreases the penetration depth and reduces a pain in retinal photocoagulation.
- Highly absorbed by hemoglobin. This is effective to photocoagulate vessels which contains high hemoglobin.
- Lowly absorbed by xanthophyll in macula.

4.2 Cautions in Ophthalmology



If the procedures in photocoagulation are improper, desired effect can not be obtained or it may damage the tissue. This occurs when the tissue to be treated can not be observed clearly. Corneal opacities, opaque ocular media, vitreous hemorrhage can interfere with the laser surgeon's view of appropriate target structures. Under this circumstances, an important tissue adjacent to the target tissue might be photocoagulated inadvertently. The treatment should be delayed until this problem is corrected. If it is not possible to delay the treatment, an alternative form of therapy should be implemented and medically indicated.

4.2.1 Cautions in photocoagulation

1. Adjustment of slit lamp

Focusing position of slit lamp microscope needs to agree with the focus of laser in laser emission. If the focusing positions disagree, laser of a specified spot size cannot be emitted on target tissue to be photocoagulated. Under this circumstance, the power density is too high or too low to perform a proper photocoagulation.

Form a habit of adjusting the surgeon's diopter and PD (Pupillary Distance) by using a focusing rod (accessory) when starting the instrument.

2. Decreasing spot size

When laser power is constant, the relation between spot size (S.S.) and power density (P.D.) can be expressed as below:

$$\text{P.D.} \propto \frac{1}{\text{S.S.}^2}$$

If the spot size is decreased to a half (laser power is fixed), the power density is increased by 4 times. Under this condition, excessive photocoagulation may occur. Spot size should be decreased with cautions.

3. Photocoagulation for pigmented tissue

All wavelengths are highly absorbed by melanin. Pigmented target tissue which contains melanin can be photocoagulated by a lower laser power. On the other hand, the target tissue which does not contain melanin needs a higher laser power for photocoagulation. Therefore, when photocoagulation is performed to the tissue which is pigmented in a different intensity, laser power needs to be set for every photocoagulation. It is recommended that laser power is initially set at a low level and then be increased gradually until the desired tissue effect is obtained.

4. Photocoagulation for opaque tissue

There may be opacities in tissues through which the laser beam must pass on its way to target tissues. Laser beam absorption by opacities may cause in advertent and undesirable thermal damage to the tissues in which the opacities are located, or it may cause in light scattering. Opacities in a patient's ocular media include mascara, face powder, corneal scars, pigment, blood on the anterior or posterior surfaces of the crystalline lens, and cataract formation. Debris should be removed from the patient's tear film prior to laser therapy, and the laser beam should be directed around rather than through the patient's ocular media opacities whenever possible.

5. Laser treatment of vascular or vascularized structures

Direct treatment of vascular or vascularized structures can cause intraocular bleeding that can impair a patient's vision as well as the surgeon's ability to complete a laser procedure. Vascular or vascularized structures should be treated with caution, using treatment patterns and parameters appropriate for the individual clinical problem.

4.2.2 Contraindications for photocoagulation

The region which should not be photocoagulated and the reason are described below.

1. Fovea centralis

Fovea centralis should not be photocoagulated by using any wavelength because it may cause a visual loss due to the degeneration of optic cell, or cause a formation of coincident scotoma at the photocoagulated tissue.

However, fovea centralis may be photocoagulated in order to prevent the visual loss caused by the progress of pathology, in case that the vision is deteriorated due to exudative age-related macular degeneration, or the active choroidal newly-formed vessel can be found.

2. Papillomacular bundle

Central visual acuity depends on the most important nerve fiber, which is coming from the fovea centralis, running horizontally on the nasal side, located in the 1/3 area on the temporal side of optic disc, and running to the posterior segment of the eye: Papillomacular bundle.

Papillomacular bundle should not be photocoagulated because it may cause a formation of coincident scotoma at the photocoagulated tissue or a central visual acuity loss. A scar should be photocoagulated with cautions because the laser may pass on the nerve fiber and the central visual acuity may be deteriorated as the nerve fiber is adjacent to the pigment epithelium.

3. Optic disc and the periphery

Optic disc should not be photocoagulated because necrosis of optic disc and visual loss may occur.

If vessels are damaged or closed by photocoagulating the retinal vessels around optic disc or choroidal vessels, optic nerve lacks nutrition to cause ischemic optic neuropathy. Periphery of optic disc should be photocoagulated with caution for the treatment parameter.

4. Retinal vessels

Photocoagulating major retinal vessels rarely causes a closure because of the cooling effect by bloodstream. However, capillary vessels has low resistance. It may cause a closure of vessels or a hemorrhage due to the damage of vessel. If vessels are closed, an optic nerve to which the vessels supply nutrition may become ischemic optic neuropathy. As ischemic optic neuropathy or visual loss due to hemorrhage may occur, a retinal vessels should not be photocoagulated.

4.3 Treatment Parameters in Ophthalmology

Ophthalmic problems are effectively treated with red, yellow or green laser photocoagulation wavelengths. Treatment parameters depend on a variety of factors including the type of tissue to be treated, the intensity of the lesion desired, and the individual pigmentation of tissue targets. Laser power should initially be set at a low level and then be increased gradually until the desired tissue effect is obtained. Typical treatment parameters are listed below.

Parameter / Clinical Indication	Laser delivery unit	Spot size (μm)	Emission time (seconds)	Power (mW)	Recommended wavelength
Diabetic retinopathy	SL, BIO	100 - 500	0.05 - 0.5	100 - 1,200	Green, Yellow, Red
Branch retinal vein occlusion	SL, BIO	100 - 500	0.05 - 0.5	100 - 500	Red
Choroidal neovascularization	SL	50 - 200	0.1 - 0.5	100 - 500	Yellow, Red
Retinopathy of prematurity	BIO	300 - 500	0.2 - 1.0	500 - 1,000	Green, Yellow, Red
Retinal tears	SL, BIO	200 - 500	0.1 - 0.5	100 - 500	Green, Yellow, Red
Iridotomy/Iridectomy	SL	50	0.02 - 1.0	50- 1,500	Green, Yellow, Red
Trabeculoplasty	SL	50	0.1	500 - 1,500	Green, Yellow, Red

SL - Slit lamp delivery unit

BIO - Binocular indirect ophthalmoscope delivery unit

4.4 Photocoagulation by Optional Delivery Unit

4.4.1 Binocular indirect ophthalmoscope delivery unit

The binocular indirect ophthalmoscope delivery unit is indicated for use in the following ophthalmic treatment.

- Diabetic retinopathy (pan-retinal photocoagulations)
- Retinopexy
- Segmental peripheral photocoagulation
- Segmental photocoagulation
- Cloudy vitreous cavities
- Pediatric retinal repairs (under general anesthesia)

[References]

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Landers, MB; Toth, CA; Semple, C; Morse, LS: “Treatment of Retinopathy of Prematurity with Laser Photocoagulation,” *Arch Ophthalmol*, IIO, 44 - 47, (January 1992).

5. TRANSPORT

Be sure to perform the procedure below before transporting the photocoagulation system.

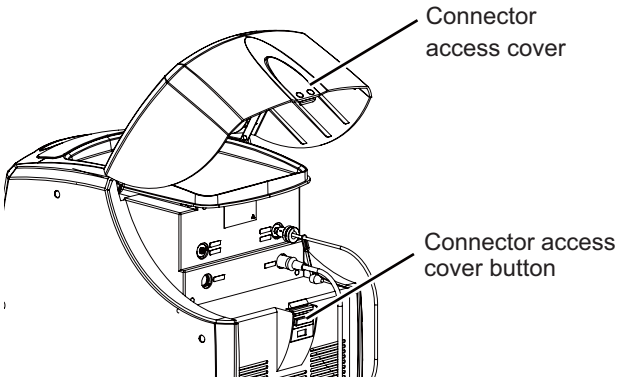
1 Turn off power to the photocoagulation system.

1) Turn off ◌̇ the key switch.
2) Turn off (◯) the master switch of the main body, then confirm that the pilot lamp is not illuminated.

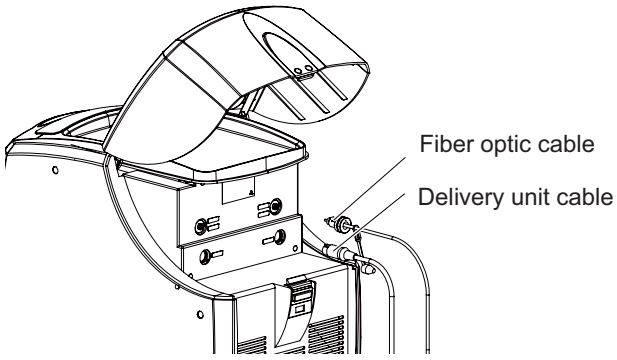
2 Remove the power cord from the main body.

Remove the power cord from the main body, coil it, and place it on the tray at the top of the main body.

3 Press the connector access cover button to open the connector access cover.

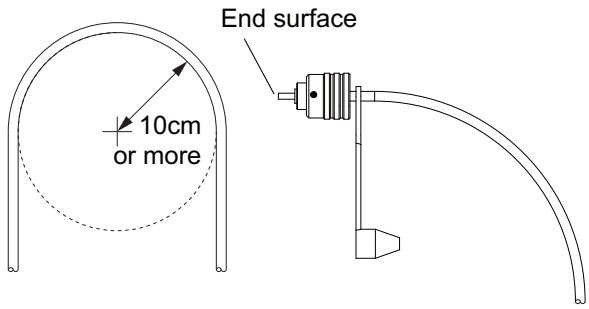


4 Remove the fiber optic cable from the main body.

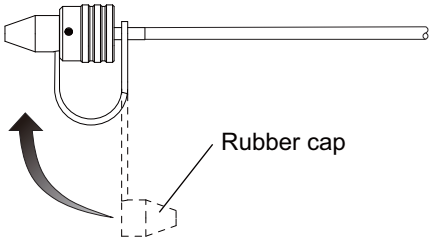


⚠ CAUTION • **Pay attention to the following points in handling of the fiber optic cable so that it is not coiled with a radius of under 10 cm.**

1. Do not coil the fiber optic cable with a radius of under 10 cm.
2. Do not soil or scratch the end surface of the plug.



1) Disconnect the fiber optic cable from the FIBER connector and put the rubber cap on the the fiber optic cable plug.

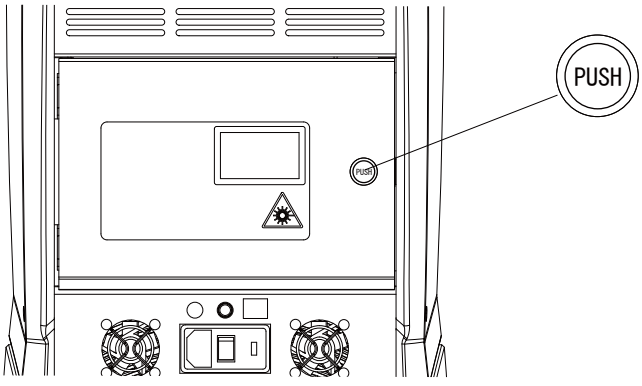


2) Remove the fiber optic cable from the fiber optic cable guide, and coil and place it on a convenient place.

5 Disconnect the delivery unit cable from the main body.

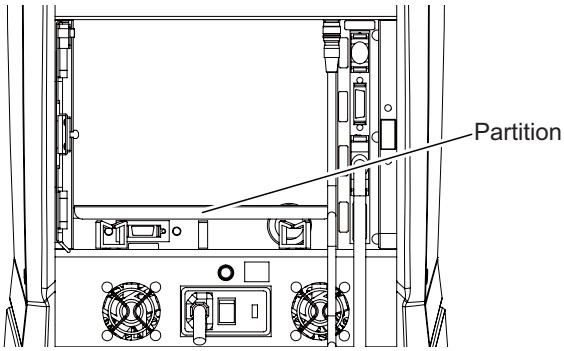
1) Disconnect the delivery unit cable from the delivery unit connector.
2) Coil the delivery unit cable and put it in a convenient place.

6 Press the rear cover button to open the rear cover.

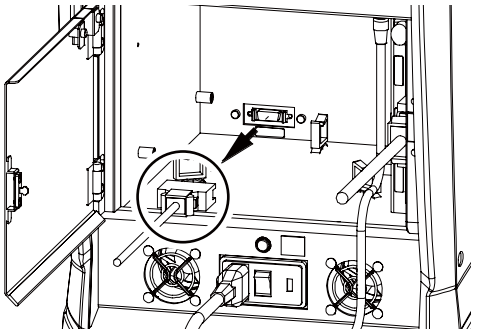


7 Remove the LCD controller from the main body.

1) Remove the partition.

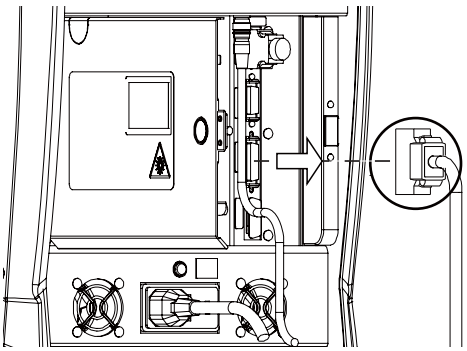


2) Disconnect the LCD controller plug from the MONITOR connector.



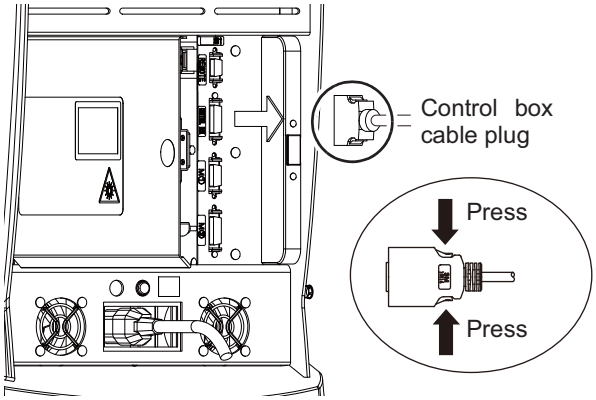
8 Disconnect the scan delivery unit cable from the main body.

1) Remove the delivery unit cable plug from the SCAN connector.
2) Coil the delivery unit cable and place it on a convenient place.



9 Remove the control box from the main body (when the optional control box is used).

1) Remove the control box plug from the CONTROL BOX connector.
2) Coil the cable around the legs of the control box and place the control box on the top board of the main body.

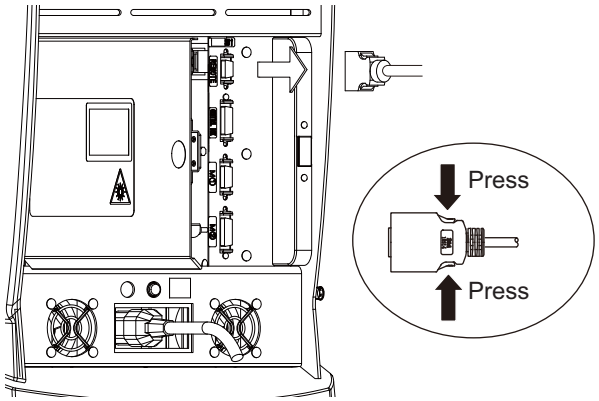


5

10 If necessary, remove the plug from the REMOTE connector.

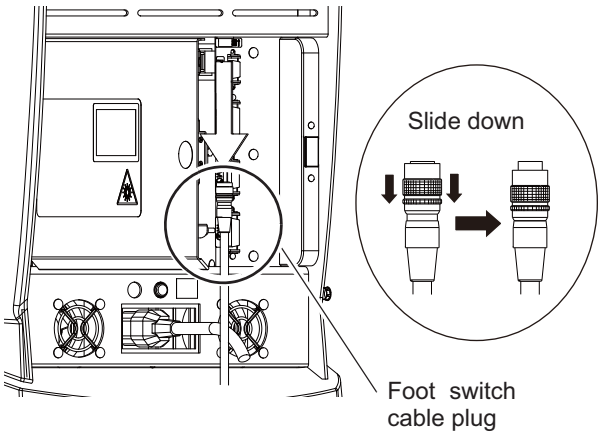
If any plug other than the short plug is connected, press the buttons on the sides of the plug and remove it.

* If a remote cable is connected, remove, coil, and place it on a convenient place.



11 Remove the foot switch from the main body.

1) Remove the foot switch cable plug from the FOOT SW connector.
2) Coil the cable and put it in the space under the foot switch cover. Then store the foot switch in the foot switch storage in the main body.



12 Unlock the casters of the main body.

Raise the lock levers on the casters to unlock the casters.

13 Transport the main body while taking care to avoid bumping it as much as possible.

⚠ **CAUTION** • **Never tilt the main body more than 10º during transport.**
The main body may fall, resulting in failure or injury.

6. MAINTENANCE

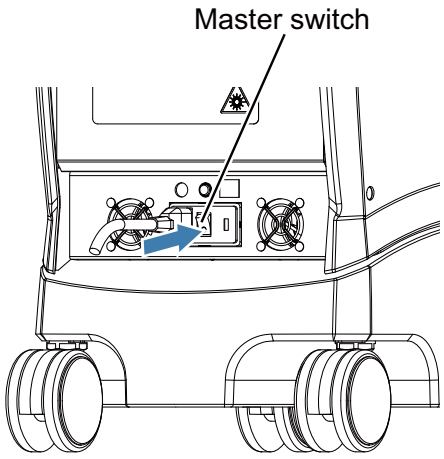
6.1 List of Consumables

Part name	Part number	Remarks
Fuse	80402-02162	250 V 2.5 A (5 mm in diameter × 20 mm)

6.2 Replacing Fuses

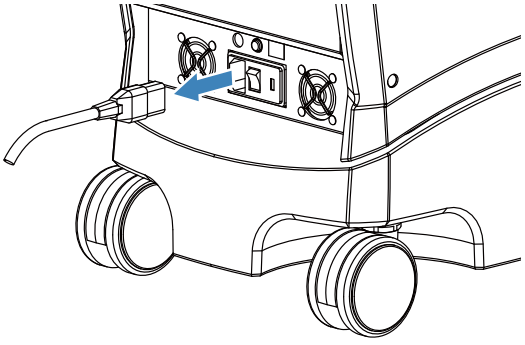
If the pilot lamp does not illuminate when the master switch of the main body is turned ON (|) even though the power cord is connected properly, fuses may be blown. In such a case, replace the fuses with new ones according to the procedure below.

1 Turn OFF (◯) the master switch and confirm that the pilot lamp goes out.

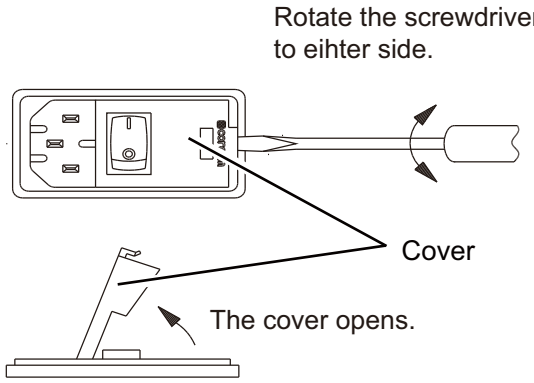


2 Remove the power cord from the power outlet.

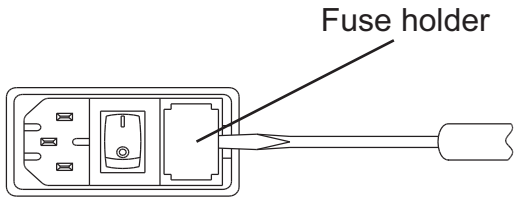
3 Remove the power cord from the power inlet of the main body.



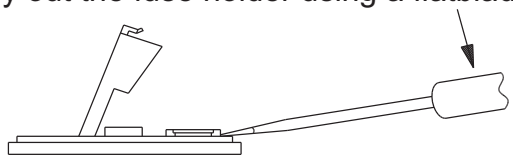
4 Insert the tip of a flatblade screwdriver into the notch of the cover, then rotate the screwdriver to either side to open the cover..

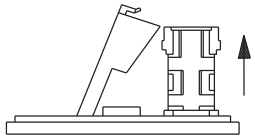


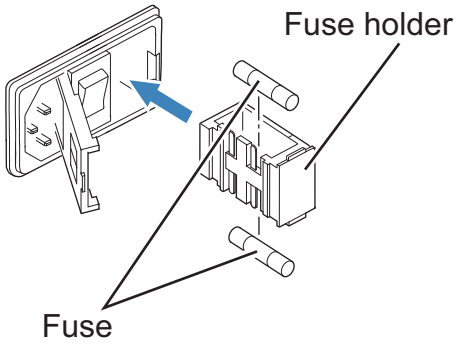
5 Remove the fuse holder and replace it with a new one.



Pry out the fuse holder using a flatblade screwdriver.







The fuse rating is as indicated by the label on the main body.

⚠ **CAUTION** • Be sure to replace both of the two fuses with new ones of the same rating.

Otherwise, the performance of the photocoagulation system may be deteriorated, or system failure or fire may result.

6 Attach the fuse holder back in position and close the cover.

7 Connect the power cord to the power inlet on the main body and the power outlet.

8 Turn ON (|) the master switch and confirm that the pilot lamp illuminates.

⚠ **CAUTION** • If the fuses blow soon again, contact your authorized distributor.

The system or the power supply may have abnormalities. NIDEK assumes no responsibility for accident caused by ignoring this abnormal condition.

6.3 Cleaning

6.3.1 Cleaning the device exterior

⚠ **CAUTION**

- **Never use an organic solvent such as thinner, or abrasive cleaner.**
  The surfaces of the main body may become ruined or scratched.
- **Be sure to wipe the exterior of the main body softly.**
  The surface of the main body may become scratched.

Clean contaminated parts of the main body exterior if necessary.

1 Soak a soft cloth in a neutral detergent, wring it out, and wipe the contaminated parts.

If the contaminated parts do not become clean, do not wipe the surface with force. In such a case, soak the cloth in the neutral detergent again, wring it out, and wipe the contaminated parts. Repeat it until the contaminated parts become clean.

2 Soak a soft cloth in water, wring it out, and softly wipe the parts wet with the neutral detergent.

If the neutral detergent cannot be removed properly, do not wipe the surface with force. In such a case, soak the cloth in water again, wring it out, and wipe the parts wet with the neutral detergent. Repeat it until the neutral detergent is removed properly.

3 Dry the wet parts with a dry, soft cloth.

6.4 Calibrating Laser Power Output (Treatment and Aiming Beams)

6.4.1 Measuring and calibrating laser power output (treatment beam)

If the difference between the indicated and actual laser power outputs is greater than tolerance, laser power needs to be calibrated.

⚠ DANGER

- **Only properly trained people are allowed to calibrate the laser output.**
- **All personnel in the operating room whose eyes are not protected by the protective filter of the delivery unit must wear safety goggles during operation of the photocoagulation system to protect their eyes.**
- **Before emitting the laser beam, make sure that no reflective object is in the optical path of the laser beam.**

  Laser beam may become reflected in unexpected directions and exposed to the personnel.

Note

- For measurement and calibration of the laser power output, proper devices are required.
- The slit lamp delivery unit can only be connected to CH 1.

  CH 1: All types of delivery units can be connected (SL, BIO)

  CH 2: Delivery units other than slit lamp delivery units can be connected (BIO)
- If the spot size is small with the red laser beam when using the slit lamp delivery unit or the attachable slit lamp delivery unit, the maximum power output is restricted as follows:

Spot size	Maximum laser power
50 µm	500 mW
60 µm	600 mW
70 µm	700 mW

6

1 Attach a power meter for laser to the delivery unit.

1) Attach the detector of the power meter securely to the laser aperture of the delivery unit.
2) Connect the cable plug of the detector to the power meter main body.

   * If necessary, connect the power cord of the power meter to a power outlet.

2 Start the photocoagulation system.

3 Prepare for measurement.

1) Turn off illumination of the delivery unit.
2) Project the aiming beam to the receiving surface of the detector, then adjust the aiming beam to an appropriate intensity with the AIMING buttons of the LCD controller or the control box (optional).
3) Adjust the aiming spot size so that the aiming spot fills the receiving surface of the detector without extending it.

* If the focus is adjusted to the receiving surface, the treatment beam may damage it.

4 Measure the minimum (50 mW), 200 mW, and the maximum power output of each color.

1) Set the laser emission conditions as follows:

   Emission time: 3.00 seconds

   Spot size: 500 µm (Slit lamp/attachable delivery unit)

   Single spot (Scan delivery unit)

   Working distance: 400 mW (Binocular indirect ophthalmoscope delivery unit)

   Laser power output: 50 mW, 200 mW, and maximum of each color

   Green laser maximum power output: 1,700 mW (1,500 mW for scan delivery unit)

   Yellow laser maximum power output: 1,500 mW

   Red laser maximum power output: 800 mW

2) Press the STATUS button of the LCD controller or the control box to set the photocoagulation system to READY mode.

3) Press the foot switch to emit the treatment beam of each color and read the measured power output.

5 Determine whether the measured power outputs of each color are acceptable compared with the set minimum (50 mW), 200 mW, and 500 mW (red only) power outputs.

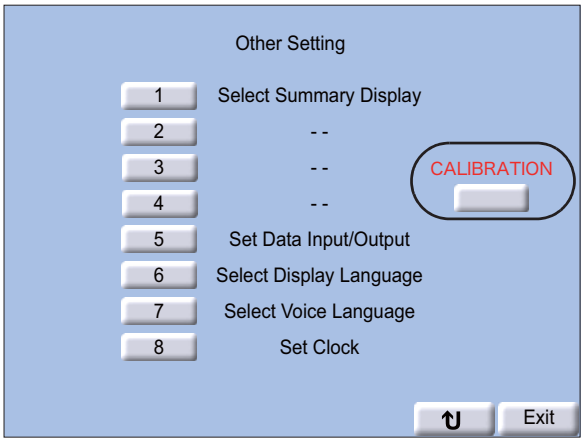
If the measured power output is within ±20% of the set power output, proceed to Step 7.

If the measured power output is outside the tolerance outside ±20%, laser power output needs to be calibrated. Proceed to Step 6.

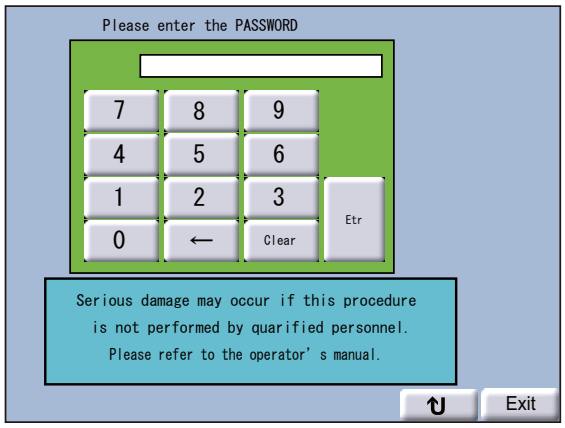
6 Enter the CALIBRATION screen.

1) Press the CUSTOM button, then the Other button to display the Other Settings screen.

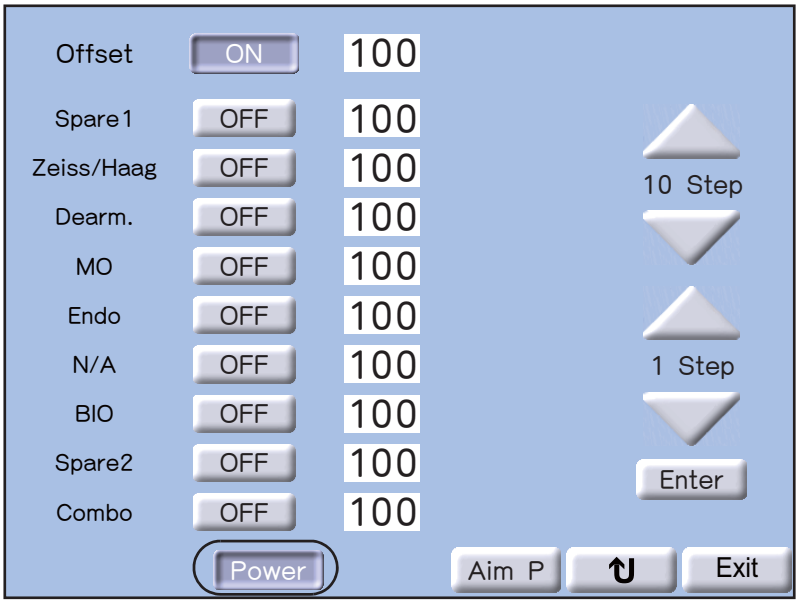
2) Press the CALIBRATION button.



3) Input the password, then press the Etr button.



7 Change the offset and gain parameters for each laser color.



1) Press the Power button.

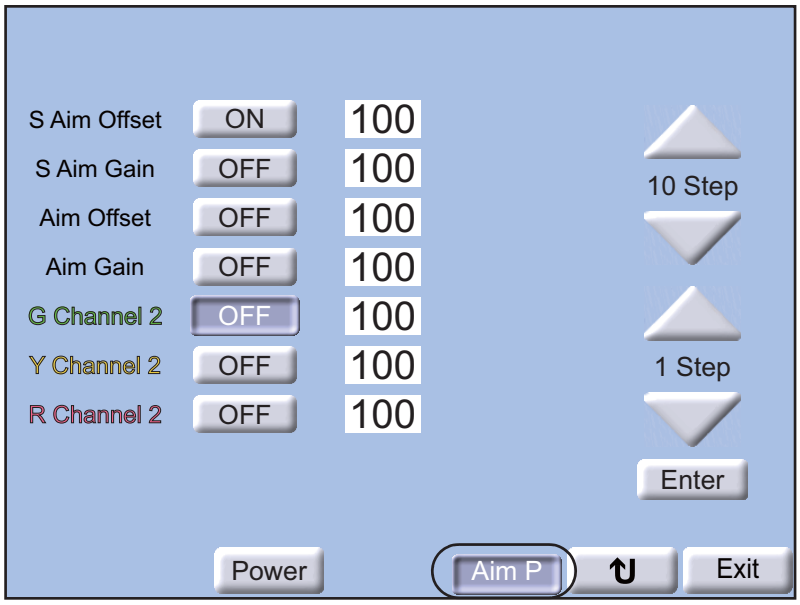
2) Press the button of the parameter to be changed to indicate "ON", then change the parameters using the up and down buttons.

   The gain for the slit lamp or scan slit lamp delivery unit is adjusted with "Zeiss/Haag" button.

Note

- Adjust the power output of 50 mW with offset adjustment, and the maximum output with gain adjustment.
- The offset is common among the delivery units.
- To increase the laser power output, raise the parameter value.

3) If the power differs between the CH 1 and 2, press the Aim P button and set the G Channel 2, Y Channel 2, and R Channel 2 parameters.



4) Return to Step 4 and confirm that the power output is correct.

6.4.2 Measuring and calibrating laser power output (aiming beam)

1 Orient the aperture of the delivery unit in a safe direction.

2 Start the photocoagulation system.

3 Prepare for power output measurement.

1) Turn off the aiming beam.
2) Project the aiming beam to the receiving surface of the detector, then adjust the aiming beam to an appropriate intensity with the AIMING buttons of the LCD controller or the control box (optional).
3) Adjust the aiming spot size so that the aiming spot fills the receiving surface of the detector without extending it.

* If the focus is adjusted to the receiving surface, the treatment beam may damage it.

4 Measure the minimum and the maximum power outputs of the aiming beam.

1) Press the AIMING button of the LCD controller or the control box (optional) to maximize the aiming beam, then read the measured power output.
2) Set the aiming beam to the minimum, and read the measured power output.

5 Determine whether the measured power outputs of the aiming beam (670 nm) are acceptable compared with the set minimum and maximum power outputs.

Criteria

Maximum aiming beam: 0.4 to 0.8 mW

Minimum aiming beam: 1/8 or less

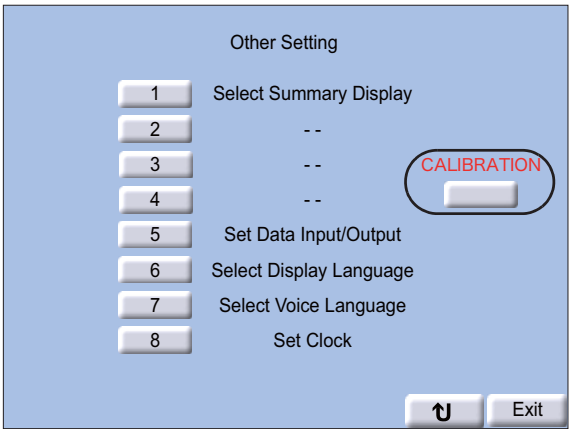
If the measured power output is within the criteria above, it is acceptable. The calibration is not needed.

If the measured power output is outside the criteria above, the calibration is needed. Proceed to Step 6.

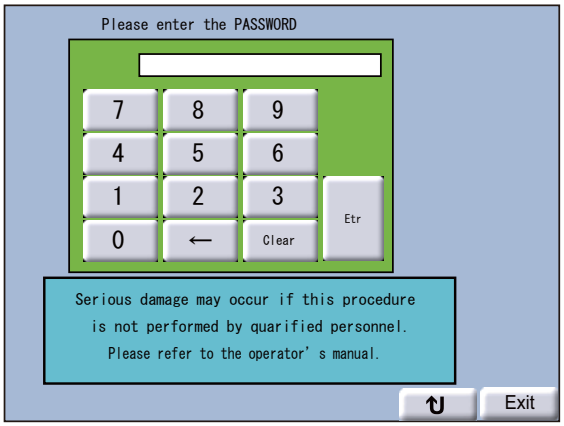
6 Enter the CALIBRATION screen.

1) Press the CUSTOM button, then the Other button to enter the Other Setting screen.

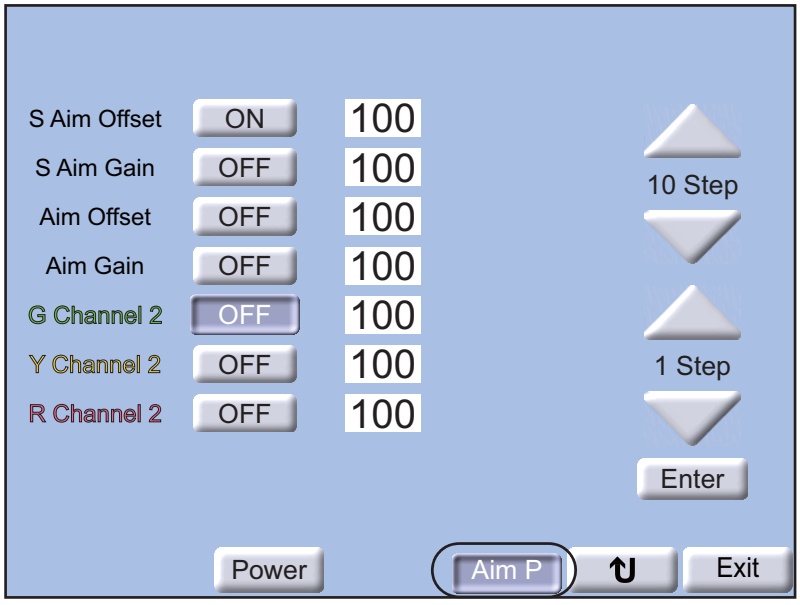
2) Press the CALIBRATION button.



3) Input the password, then press the Etr button.



7 Change the offset and gain parameters for each laser color.



1) Press the Aim P button.
2) Press the up and down buttons of the parameter to be changed to indicate “ON”, then change the parameters using the up and down buttons.

Note

- Adjust the power output of 50 mW with offset adjustment, and the maximum output with gain adjustment.
- The offset is common among the delivery units.
- To increase the laser power output, raise the parameter value.
- “S Aim Offset” and “S Aim Gain” are for the scan delivery unit.

3) Return to Step 4 and confirm that the power output is proper.

7. ADMINISTRATION AND CHECKS

7.1 Administration and Controlled Area Cautions

Appoint personnel to be in charge of storage and administration for the area in which the system is used.

One qualified administrator and one sub-administrator are needed. Instruct the personnel who use the system to observe the following.

- Administrators should appoint the personnel who use the system.
- Administrators should provide necessary knowledge of safety and training to personnel.
- Personnel who are authorized to use the system should follow the instructions of the administrators.
- Administrators should prepare the registered name list of the personnel authorized to use the system, store and manage the keys.
- Administrators should provide necessary knowledge of safety and training to personnel.
- Administrators should specify a controlled area in which the system will be used (hereafter simply called “controlled area”) and put up a notice in the area.
- In the controlled area, administrators should put up the required notices in the prominent positions indicating the name of the laser, warnings, and other necessary information.
- Any personnel who enter the controlled area (except the personnel who are on the registered name list) should get permission from the administrators and take necessary precautions before entrance.
- All personnel who enter the controlled area are advisable to take a visual acuity test before and after entrance to check for a worsening in eyesight.
- Administrators should prepare the required facilities and equipment for installation, maintenance and safety administration of the system.
- Administrators should periodically calibrate the laser beam output according to the operator’s manual at least once a year, and record the results in the form in “7.5 Laser Beam Output Calibration List” (page 91).
- Administrators should regularly perform maintenance checks as described in the operator’s manual and write down the results on the Function check list “7.4 Check List” (page 90).
- The keys should be stored in a location which is controlled by the administrator.
- Administrators should regularly calibrate the power output of the treatment beam as mentioned in this manual, and write down the results on the List of power output calibration “7.5 Laser Beam Output Calibration List” (page 91).

7.2 Management

(1) Qualified administrator and sub-administrator

	Post	Name	Signature
	•	•	•
	•	•	•
	•	•	•
	•	•	•
	•	•	•

(2) Registration of the personnel who are allowed to use the system

Post	Name	Signature
	•	•
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7.3 Function Check

Be sure to check the items below before using the photocoagulation system.
Record the results in the check list in “7.4 Check List” (page 90).

1 Appearance

Check the main body and accessories for any deformation or dirt (including on the mirror) which may interfere with the operation. Dirt made by chemicals causes the malfunction.

2 Power cable

Make sure that the power cord is properly connected to a power outlet which meets the power requirements labeled on the main body.

3 Key switch

Check if the photocoagulation system enters the STANDBY mode and a beep sounds when the master switch is turned ON (|) and the key switch is turned to the ON (⊙) position.

If the photocoagulation system does not operate as described above, contact NIDEK or your authorized distributor.

4 Display on LCD controller

Check if the LCD controller shows the Main screen when the master switch is turned ON (|) and the key switch is turned to the ON (⊙) position.

If the Main screen is not displayed on the LCD controller, contact NIDEK or your authorized distributor.

5 Numbers indicated on the control box

Check if all the digits in the control box are displayed as “ 8. “ when the master switch is turned ON (|) and the key switch is turned to the ON (⊙) position.

If any digits are not displayed as described above, contact NIDEK or your authorized distributor.

6 POWER buttons

Does the power output correctly change between 50 and the maximum (RED: 800 mW, YELLOW: 1500 mW, and GREEN: 1700 mW) in the determined increments with the operation of the POWER buttons?

Does a beep sound at the time of the change?

⚠ **CAUTION**

- **When using a slit lamp delivery unit, check the function of the POWER buttons by enlarging the spot size to the maximum. With the RED treatment beam, the maximum power output is limited by the spot size.**

7 TIME buttons

Does the emission time correctly change in the determined increments with the operation of the TIME buttons? Does a beep sound at the time of the change?

8 COLOR button

Does the laser color change in the order of … → "RED" → "GREEN" → "YELLOW" → "RED" → … every time the COLOR button is pressed? Does a beep sound at the time of the change?

9 INTERVAL buttons

Does the Single mode and interval time settings in Repeat mode change by the specified procedure with the INTERVAL buttons? Does a beep sound at the time of the changes?

10 AIMING buttons

Does the actual aiming beam and the indicated aiming beam change correctly with the AIMING buttons? Does a beep sound at the time of the change?

* Check the connection of the fiber optic cable. If it is disconnected, the AIMING level indicator displays "0", the AIMING buttons become ineffective, the TIME display shows "F.S.", and a warning message appears on the LCD controller.

⚠ **CAUTION** • **Never look the aiming beam directly or direct it toward personnel.**
Severe eye damage may occur.

11 Laser beam axis

Confirm that the intensity of the illumination spot is even around the center as the figure shown to the right and that lowering of the intensity or partial blocking of light does not occur.

12 STATUS (READY/STANDBY) button

Can the treatment beam be toggled between STANDBY and READY modes with each pressing of the STATUS button? Does a beep sound at the time of the change?

* While the AIMING level indicator is "0," the photocoagulation system cannot be placed in the READY mode even though the STATUS button is pressed. In such a case, the TIME display shows "F.S.", and a warning message appears on the LCD controller. Turn ON the aiming beam with the AIMING buttons before checking the function of the STATUS button.

13 Foot switch

Does the foot switch work properly? Is the treatment beam emitted by pressing the foot switch after the photocoagulation system is placed in READY mode by pressing the STATUS button?

⚠ CAUTION • **Never direct the aperture of the delivery unit toward personnel or flammable material since the laser beam is emitted.**
Otherwise, eyes or skin may be damaged, or fire may occur.

14 Counter reset button

Are the digits in the counter display reset to “0” by pressing this button?

Does a beep sound at the time of the change?

15 SPOT SIZE display

Is the indication displayed correctly according to the connected delivery unit as listed below?

Delivery unit type	Indication
Slit lamp delivery unit	Spot size
Binocular Indirect Ophthalmoscope delivery unit	b 10 (control box)

16 Emergency off button

Does the photocoagulation system stop when this button is pressed?

7.4 Check List

	Date of check							
Check Item								
1. Appearance								
2. Power cord								
3. Key switch								
4. LCD controller								
5. Control box								
6. POWER buttons								
7. TIME buttons								
8. COLOR button								
9. INTERVAL buttons								
10. AIMING buttons								
11. Laser axis								
12. STATUS button								
13. Foot switch								
14. Reset button								
15. SPOT SIZE display								
16. Emergency off button								

7.5 Laser Beam Output Calibration List

Item / Date	Laser color	Aiming beam Maximum output (mW)		Aiming beam Minimum output (mW)		Treatment beam Maximum output (mW)		Treatment beam Minimum output (mW)	
		Before calibration	After calibration	Before calibration	After calibration	Before calibration	After calibration	Before calibration	After calibration
	GREEN					Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	YELLOW					Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	RED					Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	GREEN					Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	YELLOW					Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	RED					Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	GREEN					Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	YELLOW					Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	RED					Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	GREEN					Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	YELLOW					Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	RED					Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	GREEN					Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	YELLOW					Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	RED					Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	GREEN					Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	YELLOW					Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	RED					Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	GREEN					Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	YELLOW					Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	RED					Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	GREEN					Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	YELLOW					Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	RED					Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:

8. TROUBLESHOOTING GUIDE

8.1 Interlock and Error Numbers

The MC-500 has the self-diagnostic function to check the system condition automatically. If any trouble occurs, the treatment beam will be blocked by the safety shutter, the power source for the laser is turned off and the EMISSION indication blinks, and the beep sounds are produced intermittently. The symptom is indicated with the interlock or error number. Interlock or error indication is displayed as “In.” or “Err” on the TIME display and the number is displayed on the INTERVAL display.
In case of trouble, inform NIDEK of Interlock or Error No. together with the symptom. They are needed for proper service. Details of them are as described on the table below.

8.1.1 Interlock

Interlock display	Symptom	Remedy
In. 4.7	High temperature in the system	Adjust the position of the system and air conditioning so that the system is in an appropriate temperature and humidity.
In. 6.3	Remote interlock	Check whether the remote connector plug is connected securely. Or check the condition of the switch connected to the plug.*
In. 12.7	Excessive power output (green)	Contact NIDEK or your authorized distributor.
In. 22.7	Excessive power output (yellow)	
In. 32.7	Excessive power output (red)	

* If the temperature or humidity has changed substantially due to transport of the system, leave the system sit for 30 minutes or more before using it.

8.1.2 Error

Error display	Symptom	Remedy
Err 1	Malfunction of photocoagulation shutter	Turn the key switch to the OFF position, then to the ON position again. If that does not solve the problem, contact NIDEK or your authorized distributor.
Err 2	Malfunction of electrically powered protective filter	
Err 3	Malfunction of safety shutter	
Err 6	Color change failure	
Err 7	Channel change failure	
Err 13	Laser power supply failure	
Err 53	Trigger switch failure	
Err 54	Fiber switch error	Remove the fiber optic cable plug and connect it again. If that does not solve the problem, contact NIDEK or your authorized distributor.

Error display	Symptom	Remedy
Err 55	Protective filter signal circuit failure	Turn the key switch to the OFF position, then to the ON position again. If that does not solve the problem, contact NIDEK or your authorized distributor.
Err 90	Program data failure	
Err 91	EEPROM data failure	
Err 93	Data failure	
Err 94	KEYLOCK error	
Err 95	CPU communication error	
Err 110	Laser malfunction (green)	
Err 113	Abnormal current for driving the laser (green)	
Err 115	Low laser power output (green)	
Err 120	Laser diode temperature control failure (green)	
Err 121	Laser head temperature control failure (green)	
Err 210	Laser failure (yellow)	
Err 213	Abnormal current for driving the laser (yellow)	
Err 215	Low laser power output (yellow)	
Err 220	Laser diode temperature control failure (yellow)	
Err 221	Laser head temperature control failure (yellow)	
Err 310	Laser malfunction (red)	
Err 313	Abnormal current for driving the laser (red)	
Err 315	Low laser power output (red)	
Err 320	Laser diode temperature control failure (red)	
Err 505	Scan position failure (FPGA)	
Err 510	Scan position failure (X axis)	
Err 511	Scan position failure (Y axis)	
Err 512	Scan position failure (X axis)	
Err 513	Scan position failure (Y axis)	

8.1.3 Error related to LAN

Error display	Remedy
LAN Write Error = 403, (0,0) DHCP Err.	Turn the key switch to the OFF position, then to the ON position again. If that does not solve the problem, contact NIDEK or your authorized distributor.
LAN Write Error = 405, (0,0) LAN Cable Connection Err.	
LAN Write Error = 451, (-220,c000005e) User Name Err.	
LAN Write Error = 451, (-220,c000006d) Password/Domain Name Err.	
LAN Write Error = 403, (-96,0) PC Name/LAN Cable/PC Err.	
LAN Write Error = 403, (-10,c00000cc) Folder Name Err.	

8.2 Indications of Misoperation

The MC-500 produces a series of beeps to inform of misoperation.
In such a case, a remedy is displayed in the LCD controller, and an abbreviated indication appears in the TIME display of the control box.
Correct the misoperation according to the remedy.

Control box indications	Contents	Remedies (Indications on the LCD controller)
A.P.	The STATUS button was pressed to place the system in the READY mode even though the aiming beam was turned off.	Press the AIMING button to emit the aiming beam.
F.S.	The AIMING button was pressed to emit the aiming beam even though the fiber optic cable was not connected.	Connect the fiber optic cable to the main body.
S.U.	The AIMING button was pressed to emit the aiming beam even though the laser beam cannot be emitted with the delivery unit or its laser mirror at the current position.	Place the delivery unit and / or its laser mirror at the positions where laser emission is possible.
S.S.	The foot switch was pressed to emit the treatment beam even though the system is in STANDBY mode.	Press the STATUS button to place the system in the READY mode.
O.d.	The delivery unit cable plug is not connected to the delivery unit connector.	Connect the delivery unit cable plug to the delivery unit connector.
HH	The temperature of the system interior is high and the occurrence of condensation is possible.	Let the system sit with the key switch ON until the HH indication disappears.

9. SPECIFICATIONS AND ACCESSORIES

9.1 Specifications

1. Treatment beam

- Type — Laser-diode-pumped solid-state laser, and diode laser
- Wavelength — Green - 532 nm
  Yellow - 577 nm
  Red - 647 nm
- Laser mode — Continuous wave
- Power output (on the cornea)
  50 mW to maximum
  (Maximum power output - Green 1,700 mW, Yellow 1,500 mW, and RED 800 mW)
  (Maximum power output (with scan function) - Green 1,500 mW, Yellow 1,500 mW, and RED 800 mW)
  Precision - ±20%
  * With the slit lamp delivery unit, scan slit lamp delivery unit, attachable delivery unit, and scan attachable delivery unit, the maximum power output of the red laser beam is limited as follows according to the spot size:
    Spot size 50 µm - 500 mW
    60 µm - 600 mW
    70 µm - 700 mW
- Power output display
  Four digits in mW
- Emission time — 0.01 to 1.00 seconds / 2.00 seconds / 3.00 seconds
  Precision ±10%
  * If the foot switch is released within the set emission time, the emission stops.
- Emission time display
  Three digits in seconds
- Repeat mode — Interval 0.05 to 1.00 second in increments of 0.05 seconds
  Precision ±10%
- Interval time display — Three digits in seconds

2. Aiming beam

- Type — Diode laser
- Wavelength — Red - 670 nm
- Laser mode — Continuous wave
- power output (on the cornea)
  15 levels
  Maximum power output (level 15) - About 0.4 to 0.8 mW
  Minimum power output (level 1) - Less than 1/8 of the maximum power output
  OFF

3. Cooling

- Type — Air cooling

4. Power supply

- Voltage — Single phase AC 230 V ±10%
- Frequency — 50/60 Hz
- Power consumption — 400 VA or less
- Power cord — 3.0 ±0.2 m long, 3P power cord with protective grounding terminal (UL hospital grade)

5. Environmental conditions (temperature and humidity)

- During transport and storage
  0 to 50°C (32 to 122°F), 10 to 95% (non-condensing)
- During use — 15 to 30°C (59 to 86°F), 30 to 75% (non-condensing)
- Others — There should be no harmful dust or smoke.

6. Dimensions and mass

- Dimensions — 300 mm (W) × 480 mm (D) × 670 mm (H) (excluding protrusions)
- Mass — 35 kg or less

7. Composition of the parts (of the MC main body) that come into contact with human body

Parts	Composition
Buttons on the control box	ABS resin
Connector access cover button	Polyacetal resin
Rear cover button	Cold-rolled steel
LCD controller, emergency off button, key switch, power switch	General electrical part

8.Service life

- Main body — 7 years from the date of the initial operation
  * Proper maintenance is necessary.

9.2 Standard Accessories

•Main body	1 unit
•Foot switch	1 unit
•Power cord	1 unit
•Other accessories	1 set
LCD controller	1 unit
Dust cover	1 unit
Operator's Manual	1 volume
Key switch (including a spare)	2 units
Power supply fuse (including two spares)	4 unit
Remote connector (Short plug)	1 units
DANGER label	1 unit

9.3 Delivery Units

•Slit lamp delivery unit

With NIDEK SL-1800 slit lamp

•Scan slit lamp delivery unit

With NIDEK SL-1800 slit lamp

•Attachable slit lamp delivery unit

For ZEISS SL130 slit lamp

For ZEISS 30SL slit lamp

For NIDEK SL-1800 slit lamp

For NIDEK YC-1800 combination

•Scan attachable slit lamp delivery unit

For ZEISS SL130 slit lamp

For ZEISS 30SL slit lamp

For NIDEK SL-1800 slit lamp

• Binocular Indirect Ophthalmoscope (HEINE OMEGA 500)

9.4 Optional Accessories

- Control box
- Beam splitter (for SL-1800, ZEISS SL 130, and ZEISS 30SL)
- TV attachment (1/3 inch)
- Co-observation unit
- Head belt
- Arm rest
- Infrared remote control
- Front delivery unit connectors
- Laser goggles

  For red - Yamamoto Kogaku Co., Ltd., YL300 He-Ne

  For yellow and green - Yamamoto Kogaku Co., Ltd., YL-717 Nd-YAG SHG
- Barcode reader
- Card reader

10. EMC

The MC-500 complies with the International Electrotechnical Commission standards (IEC 60601-1-2: 2001+A1: 2004) for electromagnetic compatibility as listed in the tables below. Follow the guidance on the tables for use of the device in the electromagnetic environment.

EMC (IEC 60601-1-2: 2001+A1: 2004)

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration - electromagnetic emissions</th></tr>
<tr><td colspan="3">The MC-500 is intended for use in the electromagnetic environment specified below. The customer or the user of the MC-500 should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The MC-500 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The MC-500 is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/
Flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer's declaration - electromagnetic immunity			
The MC-500 is intended for use in the electromagnetic environment specified below. The customer or the user of the MC-500 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage, dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	<5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MC-500 requires continued operation during power mains interruptions, it is recommended that the MC-500 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The MC-500 is intended for use in the electromagnetic environment specified below. The customer or the user of the MC-500 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Comliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms (V_1=3)	Portable and mobile RF communications equipment should be used no closer to any part of the MC-500, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=1.2\sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m (E_1=3)	$d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MC-500 is used exceeds the applicable RF compliance level above, the MC-500 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the MC-500. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the MC-500			
The MC-500 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MC-500 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MC-500 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	**80 MHz to 800 MHz** $d=1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

11. GLOSSARY

Aiming beam

Laser beam that indicates the position to which the treatment beam is to be emitted

Laser beam

Aiming beam and treatment beam

Main body

Main body of the photocoagulation system

Power output

Power output of the treatment beam (on the cornea) (Unit: mW)

Emission time

Length of time that the treatment beam is emitted (Unit: second)

Single mode/Repeat mode

In Single mode, a shot of the treatment beam is emitted in the set emission time when the foot switch is pressed. In Repeat mode, the treatment beam is repeatedly emitted in the set emission time at certain intervals while the foot switch is pressed.

Spot size

Diameter of the laser beam spot (Unit: μm)

Treatment beam

Laser beam used for photocoagulation selectable from green (532 nm), yellow (577 nm), and red (647 nm)